Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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Independent Regulatory Review Commission

(1) Agency
Environmental Protection

(2) Agency Number:
Identification Number: 7-495

IRRC Number: **3157**

(3) PA Code Cite: 25 Pa. Code Chapter 252

(4) Short Title: Environmental Laboratory Accreditation

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Laura Edinger, 717-783-8727, ledinger@pa.gov
Secondary Contact: Jessica Shirley, 717-783-8727, jesshirley@pa.gov

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

This final-form rulemaking amends the Environmental Laboratory Accreditation Regulations, 25 Pa. Code Chapter 252. The majority of the changes include clarifying the current regulatory language, removing overly restrictive and cost-prohibitive language, and adding necessary requirements that the current regulations lack. Additionally, the fee schedule included in the existing regulation does not adequately fund the Laboratory Accreditation Program as mandated by 27 Pa.C.S.§ 4104(6) (Environmental Laboratory Accreditation). The final-form rulemaking offers amendments to the following areas of the laboratory accreditation regulations: (a) Fee Structure, (b) Definitions, (c) National Environmental Laboratory Accreditation Program (NELAP) Equivalency, (d) Quality Assurance/Quality Control Procedures, (e) Analytical Procedures, (f) Record Keeping Procedures, and (g) Notification Requirements.

(8) State the statutory authority for the regulation. Include specific statutory citation.

27 Pa.C.S. § 4105(a) (dealing with Environmental Laboratory Accreditation)

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes. 27 Pa.C.S. §§4103(a); 4104(1); and 4105(a)

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The Environmental Laboratory Accreditation Regulations set forth the requirements that laboratories must meet in order to become accredited to perform testing for 12 environmental statutes administered by the Commonwealth. While completing ongoing rounds of laboratory assessments under the Chapter 252 regulation, which became effective on April 10, 2010, the Laboratory Accreditation Program discovered various portions of the regulations that could benefit from clarification. Numerous laboratories continue to be noncompliant due, in part, to a misunderstanding of some of the regulations. The Department has also added several provisions that will improve the quality of the data and ensure consistent application of the current requirements. These amendments to the regulation will benefit the entire regulated community and ensure that the laboratories generate high-quality, reliable, and well-documented environmental testing data for compliance with Department regulations.

The Department also discovered various portions of the regulations where the rules were overly restrictive and cost-prohibitive to the regulated community. These changes to the regulations will also benefit the entire regulated community. Specifically, the requirements for inorganic non-metals, basic non-potable water, and basic microbiology laboratory supervisors were changed to require less analytical testing experience to qualify as a laboratory supervisor. The Department removed the requirement for "onsite" assessments as a continuing monitor for laboratory performance, which will allow the Department to explore other cost-saving and technological advances. The Department also added several provisions to allow for the suspensions of a laboratory's accreditation instead of revocation of accreditation, thus allowing the Department more flexibility in enforcing the regulations.

The Environmental Laboratory Accreditation Act requires that the Department establish and collect fees in an amount sufficient to pay the Department's costs of implementing and administering the accreditation program. The revised fee structure included in this final-form rulemaking accounts for the number of laboratories currently seeking accreditation, the size of the laboratory's scope of accreditation, and the amount of time and cost associated with administering the accreditation program. In 2014, the Laboratory Accreditation Program began providing accreditation services for cryptosporidium, which imposes additional costs not covered by the fees promulgated in 2010. The revised fee structure separates the basic microbiology category from complex microbiology and assesses two different fees based on the complexity of the accreditation activities.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

Federal regulations exist for the accreditation of the analysis of drinking water samples but no federal regulations exist for the accreditation of the analysis of non-potable water (wastewater) or solid and chemical materials. Federal regulations cover the testing and analysis of samples from public drinking water suppliers. The federal drinking water laboratory certification program requires the use of promulgated methods for testing and analysis and includes recommended laboratory practices.

It should be noted that this final-form rulemaking is more stringent than the federal requirements for laboratory accreditation but not more stringent than the current Environmental Laboratory Accreditation Regulation. The final rule does not expand the Department's oversight or regulatory authority over environmental testing laboratories.

Federal regulations cover the testing and analysis of samples from public drinking water suppliers. The federal drinking water laboratory certification program requires the use of promulgated methods for testing and analysis and recommended laboratory practices. Some of the requirements included in the final-form regulations are more stringent than the federal standards. The federal standards for the accreditation of environmental laboratories performing testing or analysis on samples from public drinking water suppliers offer recommendations but not firm requirements. Those recommendations are included as requirements in this final-form rulemaking.

There are no federal standards or regulations for accreditation of environmental laboratory testing for non-potable water (wastewater) and solid and chemical materials. The federal regulations do mandate specific test methods and performance of the testing laboratories, but do not mandate that the laboratories seek and obtain accreditation. Because there is no federally mandated accreditation program for environmental laboratories testing non-potable water (wastewater) and solid and chemical materials and the federal certification program for testing of potable water consists mostly of recommended practices, most of these regulations are more stringent than the federal program. The final regulations contain the minimum requirements for an environmental laboratory performing testing or analysis on wastewater and solid and chemical materials as well as drinking water.

An effective laboratory accreditation program is proactive in ensuring that the data used to make critical decisions about the environment are of known and documented quality. In recent years, the Laboratory Accreditation Program (Program) has observed an increase in the number and severity of violations committed by some commercial environmental laboratories. These violations directly impact the quality of the data used for compliance decisions in the Commonwealth. The Program continues to investigate and take enforcement action against these non-compliant laboratories based on the Environmental Laboratory Accreditation Act and its regulations. Regulation is necessary to ensure that the laboratories' practices and procedures that produce the overwhelming majority of data used for environmental decisions in the Commonwealth are being performed accurately.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

These amendments are in line with those of other states. This regulation will not adversely affect Pennsylvania's ability to compete with other states. The current accreditation regulation mandates that any environmental laboratory performing compliance testing for one of the 12 statutes listed in § 252.3 (relating to scope) apply for and obtain accreditation with the Department. The amendments to this regulation amend citations to the 12 statutes listed in the Scope upon original promulgation in 2006, but does not add new statutes to the requirement for accredited testing. All laboratories performing compliance testing for any of these 12 statutes, whether physically located in the boarders of the Commonwealth or outside of those boarders are required to pay the same applications fees and meet the same accreditation requirements.

49 out of 50 states have obtained primacy from the U.S. Environmental Protection Agency (EPA) for the certification of drinking water testing laboratories. Wyoming is the only state that does not have primacy for drinking water certification, and the EPA oversees and certifies the laboratories performing drinking water compliance testing for Wyoming. The states that participate in the National Environmental Laboratory Accreditation Program (NELAP) each require environmental laboratories seeking accreditation in drinking water, non-potable water, and solids to obtain accreditation in order to perform compliance testing for their states. The NELAP states include: New Hampshire, New York,

Virginia, New Jersey, Pennsylvania, Florida, Illinois, Minnesota, Louisiana, Texas, Kansas, Utah, and Oregon.

Washington, South Carolina, California, Colorado, Oklahoma, Alabama, Wisconsin, Michigan, Ohio, Indiana, Kentucky, Georgia, West Virginia, Ohio, Connecticut, Massachusetts, Arizona, and Vermont all operate independent laboratory accreditation programs that either accept NELAP accreditation in lieu of their own state accreditation or require their own state accreditation for drinking water and non-drinking water parameters. Many states require accreditation for testing of air samples, while the Department does not require accreditation for air testing.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. (Small business is defined in Section 3 of the Regulatory Review Act, 71 P.S. § 745.3)

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in the development on drafts of the proposed and final-form regulations. The LAAC membership is made up of one representative from a municipal authority, a commercial environmental laboratory, an industrial environmental laboratory, an academic laboratory, a small environmental laboratory, an environmental engineer, a member of an association of community water supply systems, a member of an association of wastewater systems, a member with technical expertise in testing and analysis of environmental samples, and two members of the general public.

The LAAC held public meetings on December 11, 2014, March 11, 2015, June 24, 2015, September 30, 2015, and December 2, 2015 to review the Department's proposed drafts of the Chapter 252 regulations and met again on December 7, 2016 to discuss the public comments and the Department's proposal for final-form rulemaking. The LAAC and members of the public in attendance provided invaluable advice and insight to the Department during these meetings. The Department considered all comments and concurred with the majority of the recommendations made by the LAAC. The Department also agreed with many of the comments provided by the public during the public comment period. On December 7, 2016, the LAAC voted unanimously to recommend that the final-form Chapter 252 amendments be submitted to the EQB for consideration.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The types and number of entities that will be affected by the regulation are limited to those currently regulated by 25 Pa. Code Chapter 252. This final-form rulemaking does not expand the current scope of the Chapter 252 regulations. Those persons, businesses, small businesses, and organizations that may be affected by the final-form regulations include any individual, corporation, institution, or group that applies for environmental laboratory accreditation and seeks to analyze environmental samples for compliance with one or more of the 12 statutes listed in 25 Pa. Code §252.3(a). The laboratories affected by these regulations will be required to amend their current standard operating procedures and

practices to comply with the new regulations and they will be required to pay the new fees. Laboratories accredited in the basic microbiology category, basic non-potable water, and inorganic non-metals will find it easier to hire a qualified laboratory supervisor because the experience requirements have been reduced from two years to one year of experience.

A review of the USA Small Business Size Regulations under 13 CFR Chapter 1, Part 121 provides a standard for determining what constitutes a small business. The small size standard for an environmental laboratory is annual receipts of not more than $15 million. However, the Environmental Laboratory Accreditation Act and Chapter 252 regulations do not contain any requirements for the submission of financial records. The Department has no way to estimate annual receipts. The Department has historically classified environmental laboratories based on the scope of the laboratory's accreditation. There are three classifications; small laboratories and publicly owned treatment works (POTW), medium laboratories, and large laboratories. Small laboratories and POTWs perform testing in microbiology and/or basic inorganic non-metals. Medium laboratories perform testing in microbiology, inorganic non-metals, trace metals, and sometimes volatile organic compounds. Large laboratories perform testing for the same tests as medium laboratories in addition to semi-volatile organic compounds, and/or radiochemistry.

The final-form rulemaking will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories. All laboratories, particularly small laboratories, will benefit from allowing a laboratory supervisor to be absent for up to 21 days, rather than the current 16 days, and be replaced by a qualified staff member without requiring written notification to the Department. Several of the laboratory supervisor areas of experience qualifications were reduced from two years to one year. The final-form rulemaking removes the requirement for the Department to conduct "on-site" assessments, thus allowing the Department to explore and utilize advances in technology to perform off-site assessments which can substantially reduce overall costs to the Program and the regulated laboratories. The regulation also adds some specific requirements for NELAP laboratories. The current TNI Standard, which the NELAP laboratories must meet, is silent or lacking in specific requirements for several necessary standards. Requiring that all NELAP laboratories adhere to these regulations and amendments will ensure that all laboratories performing testing or analysis of compliance samples for the Department are meeting the same minimum standard.

Costs of the final-form rulemaking will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit such as large commercial laboratories and NELAP laboratories will pay a higher accreditation fee. The renewal fee for State accreditation is increased by $200 per year while the renewal fee for NELAP applicants is increased by $750 per year. The renewal application fees increase for all laboratories at a rate of approximately 30%.

Each laboratory is also responsible for paying the appropriate category fee associated with its requested scope of accreditation, such as microbiology, trace metals, volatile organics, etc. The total accreditation fee for each laboratory is the renewal application fee plus each appropriate category fee. Each category fee was increased by between $100-200 depending on the complexity of each category. The fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation.

The final-form regulations include a fee structure that is responsive to the needs of small laboratories. Specifically, increased accreditation costs for smaller laboratories will be minimal as the fees for the

Basic Non-Potable Water and Basic Drinking Water fee categories increase by $300. The current annual fee paid by these environmental laboratories is $1250.00, and the fee change will result in an annual fee of $1550.00. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. In addition, the fee structure includes changes including separation of the microbiology category into "basic" and "complex" to ensure that laboratories that are performing the more complex testing, which requires additional staff time and oversight, cover the costs of the accreditation.

Indirect costs will be related to the individual laboratory's implementation of the new requirements. Many in the regulated community are already in compliance with the additional requirements itemized in the final rulemaking and will not incur any additional costs for implementation. Others will be required to update or develop standard operating procedures and update recordkeeping procedures. Cost savings will occur in the regulated community because the new and clarified requirements will enable laboratories to better understand the applicable requirements and should reduce the number of violations found during assessments, thus reducing the amount of time and money necessary to correct these violations.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

The Department estimates approximately 450 accredited laboratories will be required to comply with these regulations. The Department estimates that the majority of these 450 accredited laboratories are considered small businesses for financial purposes. Based on the Program's designation of small, medium, and large laboratories based on scope of analytical testing, there are approximately 300 small laboratories, 80 medium laboratories and 70 large laboratories.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The impact of these regulations is minimal with regard to social impact. The final-form rulemaking will have a financial impact on the regulated laboratories and will require the laboratories to pay increased annual application fees. The fees will ensure that the program will cover the operating costs. The other changes included in the final-form rulemaking will ensure that the minimum requirements are met for the testing and analysis of environmental samples that are used by the Department to make compliance decisions. The Department must ensure that it receives reliable testing results for which it will make compliance decisions that impact the public health and the environment. Also, the final-form rulemaking removes overly restrictive and cost-prohibitive requirements where appropriate. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in this final-form rulemaking.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The regulations are the minimum standard for ensuring that the Department receives reliable testing results from which it will make compliance decisions that impact the public health and the environment. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in these regulations. The revised fee schedule ensures that the program will cover the operating costs. Failure to implement these changes will violate section 4104(6) of the Act

which requires the Program to require a fee structure in an amount sufficient to pay the Department's costs of implementing and administering the accreditation program.

The most significant benefit of this final-form rulemaking is the clear, concise, and improved regulation for the regulated community. The final-form rulemaking will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories.

Improved data quality will allow the Department, the regulated community, and the citizens of the Commonwealth to make better and more informed decisions concerning the protection of the environment and the protection of public health, safety, and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws which are covered by the regulations.

Please also see the answer to Question 15.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Additional legal, accounting, or consulting procedures will not be required. The fees associated with the regulatory requirements are an annual application fee that laboratories will be required to pay. The direct costs for compliance will be payment of the required fees. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual renewal application fees will range from $1,300 to $18,000. The cost savings will occur when the Department is able to use technology to perform assessments and reduce the amount of travel time and onsite time for the laboratories. A clearly written standard that includes specific requirements for accreditation will benefit the laboratories by reducing non-compliance and reducing the costs associated with corrective action.

To equally distribute the costs of the accreditation program based on the workload associated with the two accreditation types (State and NELAP), the renewal fee for State accreditation are increased by $200/year while the renewal fee for NELAP applicants are increased by $750/year. The costs and amount of time associated with accrediting NELAP laboratories is more than double that of a laboratory accredited in the State program. The general renewal fees will increase for all laboratories at a rate of approximately 30%. The accreditation fees for small laboratories seeking accreditation for basic drinking water or basic non-potable water will increase by $300/year. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. The accreditation fees for medium to large accredited laboratories are increased by approximately 20-30% depending on the requested scope of accreditation. Fees are required to be set in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories; with publicly owned treatment works laboratories falling into this category. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities.

The fees for the laboratories accredited in these categories will increase by only $300 over the current fees and the majority of the accredited laboratories fall into these categories. The fees assessed to a small environmental laboratory would thus be increased from an annual fee of $1250 to an annual fee of $1550.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Act requires the Department to establish fees at a level that covers the cost of administering the accreditation program. Commonwealth agencies that have accredited laboratories are not required to pay the accreditation fees.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This final-form rulemaking will require no changes to the legal, accounting, or consulting procedures for the regulated community. There are no additional reporting requirements, paperwork, forms or reports that are required to be submitted or developed for the regulated community. The regulation does include some additional recordkeeping requirements for documentation of observations made in the laboratory for microbiology incubation units, analytical balances, volumetric dispensing devices, and sample receiving documentation. These requirements are minimal and will not result in significant implementation costs.

(22a) Are forms required for implementation of the regulation?

The Department requires submission of application forms for laboratory registration, initial and renewal applications, laboratory supervisor approvals, and changes in ownership, administrative information, and quality assurance officer.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

The attached forms are as follows:

Environmental Laboratory Registration Application

Application for Environmental Laboratory Accreditation

- Part 1 – Initial/Renewal Application
- Part 2 – Methodology Requests
- Part 3 – Add/Change Laboratory Supervisor
- Part 4 – Add Field of Accreditation
- Part 5 – Changes to Laboratory Information

It should be noted that no additional forms are needed for compliance with the amendments included in this final-form rulemaking. All forms provided as attachments are in use currently by the regulated community.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2016/17	FY +1 2017/18	FY +2 2018/19	FY +3 2019/20	FY +4 2020/21	FY +5 2021/22
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0.00	0.00	0.00	0.00	0.00	0.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Savings	0.00	0.00	0.00	0.00	0.00	0.00
COSTS:	0.00	0.00	0.00	0.00	0.00	0.00
Regulated Community	0.00	$300,000	$400,00	$400,000	$400,000	$400,000
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Costs	0.00	$300,000	$400,00	$400,000	$400,000	$400,000
REVENUE LOSSES:						
Regulated Community	0.00	0.00	0.00	0.00	0.00	0.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Revenue Losses	0.00	0.00	0.00	0.00	0.00	0.00

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 (13/14)	FY -2 (14/15)	FY -1 (15/16)	Current FY (16/17)
Laboratory Accreditation	$1,606,203.61	$1,585,868.40	$1,689,858.89	$1,040,637.96

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

Of the approximately 450 regulated laboratories that fall under this regulation the Department estimates that the majority of these 450 accredited laboratories are considered small businesses for financial purposes. Based on the Program's designation of small, medium, and large laboratories based on scope

of analytical testing, there are approximately 300 small laboratories, 80 medium laboratories and 70 large laboratories.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

The majority of the regulated community is small businesses. The Laboratory Accreditation Advisory Committee membership is heavily weighted with representatives from small businesses or small regulated entities. The actual costs associated with the additional recordkeeping and other administrative costs for compliance with the final-form rulemaking are minimal. The majority of the new language includes clarifications to current requirements or items that will require additional items to be recorded during testing processes that are already being performed. No additional professional skills are necessary for these regulations.

(c) A statement of probable effect on impacted small businesses.

The probable effect on small businesses will most likely be limited to the fee increase. The fees for the smallest regulated laboratories will be increased by approximately $300. The medium to large laboratories will see an increase of between 20-30% based on the type of accreditation sought and the laboratory's requested scope of accreditation.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The final-form rulemaking is not intrusive with regard to the actual changes to the current regulations. The costs of the final-form rulemaking are associated with the fee changes. The fees were determined based on the costs associated with implementing the accreditation program, and assessed based on the amount of time the program spends to accredit a particular scope of accreditation. The fees were discussed openly during several advisory committee meetings where the public was able to express its concerns. During these advisory committee discussions, the Department explained that the costs of operating the program must be distributed appropriately throughout the applicant laboratories and that the costs must be appropriate to the size of the laboratory. The fees are representative of the Department's efforts to minimize the cost to small publicly owned laboratories and its effort to ensure that no one group has an unfair competitive advantage or disadvantage. Finally, the fees were presented as part of the proposed rulemaking and open for public comment for 30 days. The Department did not receive any negative comments from the public regarding the proposed fees or in presenting the final regulation to the LAAC.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $300/year and the majority of the accredited laboratories fall into these categories.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

There are no effective regulatory alternatives.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

(a) – (e) The majority of the regulated community affected by this regulation is small businesses. The Laboratory Accreditation Advisory Committee membership is heavily weighted with representatives from small businesses or small regulated entities and provided the Department with invaluable insight and advice during the development of this final-form rulemaking. The final-form regulations include many reductions in current requirements and clarifications to requirements that will make the regulation more easily understood. Small businesses will not find it difficult to come into compliance with the final -form rulemaking and will not require an alternate deadline for compliance. The final-form regulations do not require submission of reports to the Department. The final-form regulations do not include design or operational standards. The final-form regulations are the minimum standard for ensuring that the Department receives reliable testing results for which it will make compliance decisions that impact the public health and the environment. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in these final-form regulations.

The proposed rulemaking included a provision for checking and documenting the pH of every sample container entering the laboratory. During the public comment period and the LAAC meetings, the Department received comments regarding the negative financial impact this requirement would have on the laboratories. The Department included this provision at the recommendation of the Safe Drinking Water (SDW) Program and the EPA's instruction that an improperly collected sample is invalid and cannot be used for compliance purposes. Through discussions with the regulated community, the Department agreed to limit the pH testing requirement to those samples that require a specific pH by method, regulation, or permit, and all SDW compliance samples. Thus ensuring the protection of the public health but reducing the financial burden for non-drinking water samples. The regulated community participating in the public meeting were amenable to this solution.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be

accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Data was not the basis for this regulation.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period: 30 days

B. The date or dates on which any public meetings or hearings will be held: None

C. The expected date of delivery of the final-form regulation: Quarter 2, 2017

D. The expected effective date of the final-form regulation: Quarter 3, 2017

E. The expected date by which compliance with the final-form regulation will be required: Upon Publication

F. The expected date by which required permits, licenses or other approvals must be obtained: N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

Chapter 252, § 252.204(b) requires that the Department review and recommend any regulatory changes to the accreditation fees at least once every three years. During the fee review, the Department will also review the regulation in whole and propose any changes simultaneously.

1500-FM-BOL0101 6/2016

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Laboratories
P.O. Box 1467
Harrisburg, PA 17105-1467

Telephone (717) 346-7200
FAX (717) 346-8590

ENVIRONMENTAL LABORATORY REGISTRATION APPLICATION

The Environmental Laboratory Accreditation Act of 2002 requires that all environmental laboratories that perform testing or analysis of environmental samples required by an environmental statute register with the Department of Environmental Protection. Completion and submission of this form along with the required **fifty dollar ($50.00)** fee fulfills that requirement.

ITEM 1: Enter existing PA DEP registration/accreditation number (if known).
ITEM 2: Enter US EPA Laboratory Code. This code may be found on Water Supply (WS), Water Pollution (WP) or Discharge Monitoring Report – Quality Assurance (DMRQA) studies.
ITEM 7: Enter the person to whom the Department should send future correspondence and who will be listed as the "contact" for the facility on the Department's website.

Laboratories are reminded that all testing and analysis requirements shall be performed in accordance with the requirements of the Environmental Laboratory Accreditation Act of 2002, the environmental statutes, and any conditions imposed by the Department.

Note: Any subfacilities or remote laboratory sites are considered separate and must submit a separate application.

SUBMIT APPLICATION AND FEE (make check payable to "Commonwealth of Pennsylvania") **TO:**

Pennsylvania Department of Environmental Protection
Attn: Laboratory Accreditation Program
P.O. Box 1467
Harrisburg, PA 17105-1467

1. **Pennsylvania Accreditation ID# (if issued)** _____

2. **US EPA Laboratory Code # (if known)** _____ **e.g. PA 12345**

3. **Federal EIN Number** _____ — _____

4. **Legal Name of Applicant**

_____

5. **Mailing Address**

_____

_____

City _____

State _____ Zip Code _____ — _____

Phone _____ _____ — _____ FAX _____ _____ — _____

6. **Physical Location of Laboratory**

Number and Street _____

County _____

City _____

State _____ Zip Code _____ — _____

7. Name and Phone Number of the Laboratory Contact Person

Name _____ Phone _____ — _____

E-Mail _____

8. Laboratory Type (Check all applicable boxes)

- ☐ Commercial
- ☐ Federal
- ☐ State
- ☐ Industrial
- ☐ Mobile
- ☐ Hospital or Health-Care Facility
- ☐ Academic Institutes
- ☐ Public Water System
- ☐ Public Wastewater System
- ☐ Other _____

9. Type of Testing and Analysis Performed (Check all applicable boxes)

- ☐ pH, Residual Chlorine, Dissolved Oxygen, Flow, etc.
- ☐ Drinking Water
- ☐ Air/Emissions
- ☐ Storage Tank
- ☐ Wastewater or Discharge Monitoring
- ☐ Oil and Gas
- ☐ Hazardous Waste/Site Characterization
- ☐ Small Operator Assistance Program
- ☐ Other (Specify) _____

10. CERTIFICATION BY APPLICANT

I hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answer to the questions on this application. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Responsible Laboratory Official _____ Signature of Responsible Laboratory Official _____ Date _____

01/2017

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Laboratories
P.O. Box 1467
Harrisburg, PA 17105-1467

Telephone (717) 346-7200
FAX (717) 346-8590

APPLICATION FOR ENVIRONMENTAL LABORATORY ACCREDITATION

PART 1 – Initial/Renewal Application

Note: Any sub-facilities or remote laboratory sites are considered separate and must submit a separate application [§§ 252.201(c) and (d)]. Enclose a copy of the laboratory's quality manual with your initial application and appropriate sections of Part 2 (or list the fields of accreditation for which the laboratory is requesting accreditation). Please consult the Application Instructions for guidance regarding completion of this form. **Incomplete or inaccurate information will delay the processing of an application for accreditation and may result in denial, revocation, or lapse of accreditation.**

1. **Type of Application:**

   ☐ Initial Application—Requested Fields of Accreditation (FOAs) and completed W-9 form attached
   ☐ Renewal Application—No Changes to Scope of Accreditation requested
   ☐ Renewal Application—Changes to Scope of Accreditation requested: documentation outlining changes (additions/deletions) attached

2. **Type of Accreditation:**

   State Accreditation

   ☐ Potable/Drinking Water ☐ Non-Potable Water ☐ Solid and Chemical Materials ☐ SOAP Program

   or NELAP Accreditation (Voluntary)

   ☐ Potable/Drinking Water ☐ Non-Potable Water ☐ Solid and Chemical Materials ☐ SOAP Program

   Secondary NELAP Applicants Only

   Primary Accreditation Body (AB): _____ Date of On-Site Inspection: _____

   Primary Accreditation Body (AB): _____ Date of On-Site Inspection: _____

   Primary Accreditation Body (AB): _____ Date of On-Site Inspection: _____

3. **Laboratory Type (Check all that apply):**

   ☐ Commercial ☐ Federal ☐ Hospital or Health-Care Facility
   ☐ Industrial ☐ Public Wastewater System ☐ State
   ☐ Academic Institutes ☐ Public Water System ☐ Other _____
   ☐ Mobile License #: _____ State: __ Expiration: _____ VIN #: _____

4. **Laboratory Hours of Operation** _____

5. **Pennsylvania Laboratory ID # (if issued):** |__|__| — |__|__|__|__|__|

6. **EPA Laboratory ID #:** _____
   *If issued

7. **Federal EIN #:** |__|__| — |__|__|__|__|__|__|__|

8. **Legal Name of Applicant Laboratory:**

   _____

9. **Name of Applicant Laboratory** (as you wish it to appear on the Certificate of Accreditation)**:**

   _____

10. **Mailing Address:** (If different Billing Address, specify on an attached sheet.)

    _____

    _____

    City: _____ **State:** _____ **Zip Code:** _____

    Phone: _____ **FAX:** _____

11. **Physical Location of Laboratory** (if different from above):

Street Number: _____

_____

City: _____ **State:** _____ **Zip Code:** _____

12. **Name of Owner:** _____

13. **Address of Owner:**

_____

_____

City: _____ **State:** _____ **Zip Code:** _____

14. **Laboratory Supervisor(s)** (All individuals listed below must meet the education and experience requirements of 25 Pa. Code Chapter 252.302 and/or the TNI Standard. Laboratory supervisors are responsible for exercising day-to-day supervision of laboratory operations, testing and analysis, and reporting of results. Attach additional sheets if necessary. Secondary NELAP Laboratories–Technical Director(s) named below must match documentation from Primary AB.):

a. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

b. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

c. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

d. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

e. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

f. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

g. Name: _____ **Title:** _____

Area(s) of Supervision: _____

Email: _____ **Phone:** _____

15. **Quality Assurance Officer(s)** (Not required for State Accreditation applicants. Attach additional sheets if necessary.):

a. Name: _____ **Title:** _____

Email: _____ **Phone:** _____

b. Name: _____ **Title:** _____

Email: _____ **Phone:** _____

16. **Laboratory Personnel:** (Provide a list of laboratory personnel employed at laboratory in past 12 months who are or have been responsible for sample log-in, preparation, analysis, and/or reporting. Attach additional sheets if necessary.)

Name	Title/Position	Analytical Responsibility(ies)	Dates of Employment

17. **CERTIFICATION BY APPLICANT QUALITY ASSURANCE OFFICER(S)** (attach additional sheets, as necessary)

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

I (individual identified in Item #15) hereby certify that I am authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answers to the questions on this application. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Quality Assurance Officer (a)	Signature Quality Assurance Officer	Date
Name of Quality Assurance Officer (b)	Signature Quality Assurance Officer	Date

18. **CERTIFICATION BY APPLICANT LABORATORY SUPERVISOR(S)** (attach additional sheets, as necessary)

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania. In accordance with 25 Pa Code Chapter 252 § 252.301(a), "The Department will consider the laboratory supervisor of an environmental laboratory as the individual listed on the laboratory's application for accreditation for which the Department has reviewed and approved the individual's

qualifications." All laboratory supervisors identified in Item #14 of this application must sign the certification statement below.

I (individual(s) identified in Item #14) hereby certify that I am authorized to sign this application and have been designated by the laboratory/owner to act as a laboratory supervisor and that there are no misrepresentations in the answers to the questions on this application. I understand and agree to follow the requirements and perform the functions of a laboratory supervisor, as outlined in 25 Pa Code Chapter 252 or the TNI Standard, based on the accreditation type sought by the applicant laboratory.

Failure to meet the requirements of 25 Pa. Code Chapter 252 could result in denial, suspension, or revocation of your laboratory's accreditation and is due cause for civil penalties as established by the Environmental Laboratory Accreditation Act (27 Pa C.S. §§ 4101 – 4113). As indicated below with a check-mark, I hereby certify that I have read following:

Laboratory Supervisor:							
a	b	c	d	e	f	g	**Laboratories Seeking Primary or Secondary NELAP Accreditation**
☐	☐	☐	☐	☐	☐	☐	TNI Standard, V1M1 – PT, V1M2 – QS, and appropriate technical modules
☐	☐	☐	☐	☐	☐	☐	25 Pa. Code Chapter 252, Subchapters B, E, F, and G
							Laboratories Seeking State Accreditation
☐	☐	☐	☐	☐	☐	☐	25 Pa. Code Chapter 252
							Laboratories Seeking Drinking Water Accreditation
☐	☐	☐	☐	☐	☐	☐	25 Pa. Code Chapter 109, § 109.810

I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Supervisor (a) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (b) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (c) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (d) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (e) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (f) (however named)	Signature Supervisor (however named)	Date
Name of Supervisor (g) (however named)	Signature Supervisor (however named)	Date

APPENDIX A
Fee Calculation

In accordance with 25 Pa. Code Chapter 252, § 252.204(a), "The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation. A check must be payable to "Commonwealth of Pennsylvania."[1] A complete fee includes payment of the appropriate Application Fee in addition to all appropriate Matrix Category Fees."

Initial Application Fee (State)[2]	$ 750	☐	Initial Application Fee (NELAP)[2]	$ 2,500	☐
Renewal Application Fee (State)	$ 500	☐	Renewal Application Fee (NELAP)	$ 2,000	☐

1st Matrix[3]			2nd Matrix[3]			3rd Matrix[3]		
BDW	$ 650	☐						
BNPW	$ 750	☐						
Asbestos	$ 400	☐	Asbestos	$ 350	☐	Asbestos	$ 300	☐
Micro	$ 500	☐	Micro	$ 450	☐	Micro	$ 400	☐
Trace Metals	$ 550	☐	Trace Metals	$ 500	☐	Trace Metals	$ 450	☐
Non-Metals	$ 600	☐	Non-Metals	$ 550	☐	Non-Metals	$ 500	☐
VOC	$ 650	☐	VOC	$ 600	☐	VOC	$ 550	☐
SEMI	$ 1500	☐	SEMI	$ 1400	☐	SEMI	$ 1300	☐
Dioxin	$ 650	☐	Dioxin	$ 600	☐	Dioxin	$ 550	☐
RAD	$ 750	☐	RAD	$ 700	☐	RAD	$ 650	☐
WETT	$ 700	☐						
Sub-Totals		_____			_____			_____

GRAND TOTAL (Application Fee + Matrix Category Fees) _____

[1] In addition to the appropriate fees, out-of-State environmental laboratories shall reimburse the Department for out-of-State travel related to expenses necessitated by the on-site assessment process. See § 252.204(e)

[2] Applications submitted by a laboratory that does not have a valid accreditation certificate from the PA-DEP are considered initial applications and require payment of the Initial Application Fee.

[3] "Matrix" refers to Drinking Water, Non-Potable Water, and Solid & Chemical Materials. Laboratories must pay the appropriate fee based on the number of matrices for which the laboratory requests accreditation.

Example Fee Calculation:

XYZ Laboratory wants to renew its State accreditation certificate and performs testing of Whole Effluent Toxicity (WETT), Inorganic Non-Metals and VOCs in drinking water and non-potable water and also performs testing of Trace Metals in all three matrices. XYZ Laboratory would be responsible for the following fee:

Application Fee – Renewal Application for State Accreditation	$ 500
Whole Effluent Toxicity (WETT)	$700
Trace Metal Category (3 Matrices)	$ 1,500
Inorganic Non-metal Category (2 Matrices)	$ 1,150
Volatile Organic Chemicals (2 Matrices)	$ 1,250
Total (Matrix Category Fees + Application Fee)	**$ 5,100**

APPENDIX B
Guidance Documents

The Department has developed guidance documents and other compliance assistance aids that describe the various accreditation requirements that laboratories must meet. These documents are available on the Department's website at www.dep.pa.gov/business/otherprograms/labs under "Laboratory Accreditation Program." Below is a list of some of the documents that the Laboratory Accreditation Program strongly recommends that laboratories read and understand.

All Laboratories Seeking Accreditation
- ☐ Part 1 – Initial/Renewal Application Instructions
- ☐ Part 3 – Add/Change Supervisor Instructions
- ☐ Part 4 – Addition of Field of Accreditation Instructions
- ☐ Part 5 – Change to Laboratory Information Instructions

Laboratories Seeking Primary NELAP and State Accreditation
- ☐ Corrective Action Report FAQ
- ☐ On-Site Assessment Guidance
- ☐ Proficiency Testing Guidance for Labs

Laboratories Seeking Drinking Water Accreditation for Chemistry
- ☐ Request to Report Qualified DW Results Instructions
- ☐ SDWA Composite Analysis FAQ
- ☐ Memo to DW Accredited Labs RE: SDWA Reporting and Notification Requirements

Laboratories Seeking Drinking Water Accreditation for Microbiology
- ☐ Memo to DW Accredited Labs RE: SDWA Reporting and Notification Requirements
- ☐ Notice to DW Micro Labs RE: SDWA Microbiology Results
- ☐ Coliform Density Calculation FAQ

Laboratories Seeking Secondary NELAP Accreditation
- ☐ Secondary NELAP FAQ

12/2014

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COMMONWEALTH OF PENNSYLVANIA
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Bureau of Laboratories
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Harrisburg, PA 17105-1467

Telephone (717) 346-7200
FAX (717) 346-8590

APPLICATION FOR ENVIRONMENTAL LABORATORY ACCREDITATION

PART 2 – Methodology Requests

1. **Pennsylvania Laboratory ID:** ___ ___ – ___ ___ ___ ___ ___

6. **Methodology Requests** (include additional sheets as necessary, or provide the same information in a spreadsheet or other document):

Matrix(ces)	Method & Rev#	Analyte	SOP*	IDOC*	PT*

* Leave these columns blank. For Department Use Only.

05/2012

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Bureau of Laboratories
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Harrisburg, PA 17105-1467

Telephone (717) 346-7200
FAX (717) 346-8590

APPLICATION FOR ENVIRONMENTAL LABORATORY ACCREDITATION

PART 3 – Add/Change Laboratory Supervisor

Note: An accredited environmental laboratory must have at least one qualified laboratory supervisor (or Technical Director, for NELAP) who meets the qualifications outlined in 25 Pa. Code, Chapter 252 or the 2009 TNI Standard. Enclose the appropriate documents demonstrating that the individual proposed on this form is qualified to perform the function of a laboratory supervisor (however named). **Incomplete or inaccurate information will delay the processing of an application for addition or replacement of a laboratory supervisor and may result in denial, revocation, or lapse of accreditation.**

Terms and Definitions

Laboratory Supervisor (or Technical Director)—A technical supervisor of an environmental laboratory who supervises laboratory procedures and reporting of analytical data. This individual must meet the education and experience requirements of the applicable standard (State or NELAP) for which the laboratory seeks to obtain and/or maintain accreditation.

Lead Supervisor—Laboratory supervisor (or technical director) designated by management/ownership to be listed on all official correspondence from the Department. This supervisor is also listed as the contact for the laboratory on the DEP website. "Lead Supervisor" is an unofficial term used by the Department to identify the individual to whom official correspondence is addressed. This individual must meet the education and experience requirements for a supervisor.

Primary Supervisor—Laboratory supervisor who exercises actual day-to-day supervision for one or more areas of the laboratory's accreditation.

Alternate Supervisor—Individual meeting the qualifications of a laboratory supervisor for one or more areas of the laboratory's accreditation and who performs the function of a laboratory supervisor when the primary supervisor is absent.

Laboratory Information:

1. **Pennsylvania Laboratory ID:** ☐☐ — ☐☐☐☐☐
   Use separate application form for each individual Laboratory ID#.

2. **Laboratory Name:** (as it appears on the Certificate of Accreditation)

3. **Type of Accreditation:**
   - ☐ State Accreditation (Chapter 252)
   - ☐ NELAP Accreditation

Proposed Supervisor Information:

4. **Type of Application:** (check all that apply)
   - ☐ Replace a Laboratory Supervisor (includes removal of current supervisor)
   - ☐ Add a Laboratory Supervisor
   - ☐ Amend Supervisory Responsibilities of Current Laboratory Supervisor
   - ☐ Designate a new "Lead Supervisor"

5. **Proposed Laboratory Supervisor:** (Use separate application form for each proposed laboratory supervisor)
   Name: **Phone:** ☐☐☐ ☐☐☐ — ☐☐☐☐ x ☐☐☐

   Email:

6. **Does this Proposed Laboratory Supervisor replace a previously designated Laboratory Supervisor?**
   ☐ Yes ☐ No If "Yes", specify previous laboratory supervisor's name below.

7. **Proposed Area(s) of Supervision:** (check all that apply)

☐ Microbiology	☐ Volatile Organic Compounds	☐ Whole Effluent Toxicity
☐ Asbestos	☐ Extractable and Semi-Volatiles	☐ Radiochemistry
☐ Inorganic Non-Metals	☐ PCBs	☐ Micro (limited to: Fecal, TC, E.coli, HPC)
☐ Trace Metals	☐ Dioxin	☐ Other _____
☐ Other _____	☐ Other _____	☐ Other _____

8. **Type of Supervision:** (Laboratories are required to designate an alternate laboratory supervisor if the Primary Supervisor is absent for longer than 16 calendar days. NOTE: Laboratories are required to notify the Laboratory Accreditation Program if a Primary Laboratory Supervisor's absence exceeds 30 calendar days.)

☐ Primary ☐ Alternate If both, please specify Primary Area(s): _____

9. **Will this individual be considered the "Lead Supervisor"?** (The Lead Supervisor must meet the qualifications of a Laboratory Supervisor and must be performing the functions of a Laboratory Supervisor.)

☐ Yes ☐ No

10. **Effective Date(s) of Supervisory Responsibilities:** _____

11. **Physical Address for Proposed Laboratory Supervisor:** (if different from the physical location of laboratory)

_____

_____

City _____

State _____ **Zip Code** _____ — _____

12. **Analytical Experience:** (Applicant MUST complete the following table. Provide a range of dates for the specific time period for which analytical experience was obtained. Attach additional sheets, if necessary.)

Method	Technology	Analyte/Class of Analyte	Dates
e.g.: SM 5210B	*e.g.: electrode*	*e.g.: BOD/CBOD*	*e.g.: 6/99-Present*

13a. **Education:** (Laboratory Supervisors are required to have obtained specific educational qualifications depending on the area of supervision. Complete the following table with regard to college semester credit-hours of education. Attach additional sheets, if necessary.)

School Name	Degree Conferred	# Chemistry[1] Credits	# Biology[2] Credits	# Science[3] Credits (specify type)
e.g.: University of Pittsburgh	*e.g.: BS*	*e.g.: 44*	*e.g.: 4*	*e.g.: N/A*

1 Courses that may be considered as "Chemistry" must be listed as CHE, CHM, CHEM, CH, BCHEM, BC or other clear designation.
2 Courses that may be considered as "Biology" must be listed as BIO, BB, BIOSC, BIOL, MIC, MICRO, or other clear designation.
3 Courses that may be considered as "Science" include: chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences, or engineering.

13b. **Certified Operator Provision:** (This provision is limited to an individual acting as the laboratory supervisor of a drinking water, wastewater, or industrial waste treatment facility.)

Operator Certificate #: _____ Expiration Date: _____

Certificate Type: ☐ Drinking Water ☐ Wastewater ☐ Other, please specify: _____

14. **Attachments to be included with application:**

☐ Resume or other summary of analytical experience and where it was obtained (required)
☐ College Transcripts (required, unless claiming supervision under the Certified Operator Provision)
☐ Operator's Certificate (required, if applying under Operator Certification Provision)

15. CERTIFICATION BY APPLICANT LABORATORY

As an authorized representative of the environmental laboratory, I hereby understand and acknowledge that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations, and the Environmental Laboratory Accreditation Act, Act of June 9, 2002, P.L. 596, No. 90, 27 Pa. C.S. §§ 4101-4113 and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

I hereby certify that I am authorized to sign this application and designate the individual named in Item #5 on this application to act as a laboratory supervisor at the laboratory named in Item #1 of this application and that there are no misrepresentations in the answers to the questions on this application. I understand and agree to follow the requirements of 25 Pa Code Chapter 252 or the 2009 TNI Standard, based on the accreditation type sought by the laboratory. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Laboratory Representative (however named)	Signature of Laboratory Representative (however named)	Date

16. CERTIFICATION BY APPLICANT SUPERVISOR (individual named in item #5)

The proposed supervisor understands and acknowledges that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

I hereby certify that I am authorized to sign this application and have been designated by the laboratory/owner to act as a laboratory supervisor and that there are no misrepresentations in my answers to the questions on this application. I understand and agree to follow the requirements and perform the functions of a laboratory supervisor, as outlined in 25 Pa Code Chapter 252 or the 2009 TNI Standard, based on the accreditation type sought by the laboratory I propose to supervise. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Proposed Supervisor (however named)	Signature of Proposed Supervisor (however named)	Date

06/2013

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DEPARTMENT OF ENVIRONMENTAL PROTECTION

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DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Laboratories
P.O. Box 1467
Harrisburg, PA 17105-1467

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FAX (717) 346-8590

APPLICATION FOR ENVIRONMENTAL LABORATORY ACCREDITATION

PART 4 – Addition of Field of Accreditation (FOA)

NOTE 1: The Department will not process Add FOA applications that do not include a SOP and IDOC for each requested FOA. (Not required for Secondary NELAP applicants.) **Incomplete or inaccurate information will delay the processing of an application for accreditation and may result in denial of application.**

NOTE 2: Laboratories may choose to perform PT studies before or after the submission of the add FOA application form. The PT studies must meet all requirements of 25 Pa Code Chapter 252, § 252.501.

NOTE 3: Any Add FOA application that results in the expansion of the laboratory's accreditation requests beyond the Accreditation Categories paid in the most recent Application for Accreditation (Initial or Renewal) will require payment of the appropriate category fee in addition to the Addition of FOA Fee. The Add FOA fee is not required when Part 4—Add FOA applications are submitted with Part 1—Initial/Renewal Applications. Secondary NELAP applicants are assessed the $250.00 Add FOA fee after the fifth (5th) Add FOA Application.

NOTE 4: Should the Department determine that a supplemental on-site assessment is required prior to a final determination of the Add FOA application, the Department will provide an invoice for payment of the Supplemental On-site Assessment Fee of $500.00. The Supplemental On-site Fee must be paid before the Department will schedule a supplemental on-site assessment.

1. **Pennsylvania Laboratory ID:** | | | — | | | | | |

2. **Laboratory Name:**

3. **Requirements for a complete Add FOA Application for Primary NELAP & State Applicants:**

- ☐ SOPs for all requested FOAs
- ☐ IDOCs for all requested FOAs
- ☐ Completed Proficiency Testing Studies, as required by the FoPT Tables or provide the anticipated date of completion
- ☐ $250.00 Addition of Field of Accreditation Fee (not required when submitted with a Part 1—Initial/Renewal Application)
- ☐ Fee for any new accreditation category associated with the Add FOA, as appropriate (see § 252.204)

4. **Requirements for a complete Add FOA Application for Secondary NELAP Applicants:**

- ☐ Valid Scope of Accreditation from a NELAP Recognized Accreditation Body with requested FOAs highlighted or otherwise clearly identified
- ☐ Fee for any new accreditation category associated with the Add FOA, as appropriate (see § 252.204)
- ☐ $250.00 Addition of Field of Accreditation Fee (fee waived for most Secondary NELAP applicants, see NOTE 3. Fee not required when submitted with a Part 1—Initial/Renewal application)

5. **CERTIFICATION BY APPLICANT**

As an authorized representative of the environmental laboratory, I hereby understand and acknowledge that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations, and the Environmental Laboratory Accreditation Act, Act of June 9, 2002, P.L. 596, No. 90, 27 Pa. C.S. §§ 4101-4113 and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

Name of Laboratory Representative (however named)	Signature of Laboratory Representative (however named)	Date

6. **Additional Field(s) of Accreditation** (include additional sheets as necessary):

Matrix(ces)	Method & Rev#	Analyte	CAS #	SOP*	IDOC*	PT*

* Leave these columns blank. For Department Use Only.

01/2017

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Harrisburg, PA 17105-1467

Telephone (717) 346-7200
FAX (717) 346-8590

APPLICATION FOR ENVIRONMENTAL LABORATORY ACCREDITATION

PART 5 – Changes to Laboratory Information

Note: Any sub-facilities or remote laboratory sites are considered separate and must submit a separate application [§§ 252.201(c) and (d)]. **Incomplete or inaccurate information will delay the processing of an application for accreditation and may result in denial, revocation, or lapse of accreditation.**

1. **Pennsylvania Laboratory ID:** ☐☐ — ☐☐☐☐☐

2. **Type of Application:** (check all that apply)

   ☐ Change in Administrative Information (change in Laboratory Name or Address)—Complete Appendix A
   ☐ Ownership Transfer Application—Complete Appendix B
   ☐ Change in Quality Assurance Officer—Complete Appendix C

3. **Attachments to be included with Appendix A—Change in Administrative Information:**

   ☐ $150.00 Change in Administrative Information Fee (not required if submitted in conjunction with Appendix B—Ownership Transfer Application)
   ☐ Valid Scope of Accreditation from a NELAP Recognized Accreditation Body confirming all requested changes (Secondary NELAP applicants only)

   NOTE: Changes limited to phone or fax number, e-mail addresses, or EPA ID# may be provided on a separate sheet and do not require completion of a Part 5—Changes to Laboratory Information application form or payment of fee.

4. **Attachments to be included with Appendix B—Ownership Transfer Application:**

   ☐ Summary of Personnel and Responsibilities (must specifically outline all laboratory personnel, their responsibilities and any changes to or reassignment of management or analytical staff)
   ☐ Summary of Equipment and Records (must specifically outline all equipment and Chapter 252/TNI records that will be maintained and any changes such as purchase or consolidation of equipment)
   ☐ Summary of Operations (must specifically outline the laboratory's operations and any changes to quality documents, operating procedures, sample reporting, etc.)
   ☐ Completed W-9 Form
   ☐ $150.00 Ownership Transfer Fee

5. **Attachments to be included with Appendix C—Change in Quality Assurance Officer:**

   ☐ Confirmation from Primary NELAP Recognized Accreditation Body of the change in personnel (Secondary NELAP applicants only)

6. **CERTIFICATION BY APPLICANT**

   As the laboratory supervisor of the environmental laboratory, I hereby understand and acknowledge that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations, and the Environmental Laboratory Accreditation Act, Act of June 9, 2002, P.L. 596, No. 90, 27 Pa. C.S. §§ 4101-4113 and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

Name of Laboratory Supervisor (however named)	Signature of Laboratory Supervisor (however named)	Date

Appendix A

Change in Administrative Information

A1. Legal Name of Laboratory:

A2. Laboratory Name (as it should appear on the Certificate of Accreditation, if different from Item #A1):

A3. Mailing Address: (if different Billing Address, specify on an attached sheet)

City

State **Zip Code** —

A4. Physical Location of Laboratory: (if different from above)

Street Number:

City

State **Zip Code** —

A5. Phone Number: —

A6. EPA Laboratory ID #: _____

A7. Federal EIN #: —

A8. Effective Date of the Name Change: _____

A9. Effective Date of the Address Change: _____

Appendix B

Ownership Transfer Application

B1. Legal Name of Laboratory:

B2. Laboratory Name (as it should appear on the Certificate of Accreditation, if different from Legal Name):

B3. EPA Laboratory ID #: _____

B4. Federal EIN #: ___ — ___

B5. Name of New Owner:

B6. Address of New Owner:

City

State **Zip Code** —

B7. Effective Date of the Ownership Change: _____

B8. Acknowledgement by New Owner:

I understand and acknowledge that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania. I also understand that in accordance with:

- 27 PA C.S. § 4106(b) of The Act of June 29, 2002 (P.L. 596, No. 90) (dealing with environmental laboratory accreditation), "General Requirements—An environmental laboratory shall have the staff, management structure, equipment, quality assurance and quality control procedures and recordkeeping procedures necessary to ensure that the environmental laboratory generates valid and accurate test results in accordance with all conditions of accreditation and this chapter."
- 25 Pa. Code § 252.202, "(a) Within 30 calendar days following the change in laboratory ownership, an accredited environmental laboratory shall do the following: (3) Agree to correct any violations that exist at the time of the sale or transfer in accordance with a schedule that is acceptable to the Department," and "(b) Enforcement actions will be transferred with the accreditation."

I hereby certify that I am the owner of the laboratory named in item B2 and authorized to sign this application and that there are no misrepresentations in the information provided with this application. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Owner	Signature Owner	Date

Appendix C

Change in Quality Assurance Officer

C1. Laboratory Name:

C2. Type of Accreditation:

☐ State Accreditation (Chapter 252)
☐ NELAP Accreditation

C3. Type of Application:

☐ Replace a QA Officer (includes removal of current QA Officer)
☐ Add a QA Officer

C4. New Quality Assurance Officer:

Name: **Phone:** ___ ___ — ___ x ___

Email:

C5. Quality Assurance Officer to be Removed (if applicable):

Name:

C6. Effective Date of the QA Officer Responsibilities: _____

C7. Certification by QA Officer:

I understand and acknowledge that the laboratory is required to be continually in compliance with the Commonwealth of Pennsylvania Department of Environmental Protection regulations and is subject to the enforcement and penalty provisions of the Commonwealth of Pennsylvania.

I hereby certify that I am authorized to sign this application and that there are no misrepresentations in my answers to the questions on this application. I understand that false statements made in this application are subject to the provisions of 18 Pa. C.S. Section 4904(b) (unsworn falsification to authorities).

Name of Quality Assurance Officer	Signature Quality Assurance Officer	Date

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
MAY 11 2017
Independent Regulatory Review Commission

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

By:
(Deputy Attorney General)

DATE OF APPROVAL

☐ Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-495

DATE OF ADOPTION APRIL 18, 2017

BY [signature]

TITLE PATRICK MCDONNELL
ACTING CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality Executive or Independent Agencies

BY [signature]

MAY 05 2017
DATE OF APPROVAL

(Deputy General Counsel)
~~(Chief Counsel - Independent Agency)~~
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Environmental Laboratory Accreditation

25 *Pa. Code,* Chapter 252

Notice of Final-Form Rulemaking
Department of Environmental Protection
Environmental Quality Board
(25 Pa. Code Ch. 252)
(Environmental Laboratory Accreditation)

The Environmental Quality Board (Board) by this order amends 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The amendments clarify existing requirements, remove or amend overly restrictive and cost-prohibitive requirements, and include additional requirements necessary for laboratory accreditation. The final-form rulemaking also revises the current fee structure found at 25 Pa. Code § 252.204.

This order was adopted by the Board at its meeting of April 18, 2017.

A. *Effective Date*

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin.*

B. *Contact Persons*

For further information contact Aaren S. Alger, Chief, Laboratory Accreditation Program, P.O. Box 1467, Harrisburg, PA 17105-1467, (717) 346-8212, or William S. Cumings, Jr., Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.pa.gov (Select "Public Participation," then "Environmental Quality Board").

C. *Statutory Authority*

This final-form rulemaking is being made under the authority of 27 Pa. C.S. § 4105(a), which directs the Board to adopt regulations as necessary to implement 27 Pa. C.S. Chapter 41 (relating to Environmental Laboratory Accreditation) (the Act) and § 1920-A of The Administrative Code of 1929 (71 P.S. §510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Purpose*

The regulations governing environmental laboratory accreditation at 25 Pa. Code Chapter 252 became effective on January 28, 2006 and were amended on April 10, 2010. While completing ongoing rounds of laboratory assessments under these regulations, the Laboratory Accreditation Program ("Program") discovered various provisions that are unclear or where the rules are lacking sufficient detail to ensure full compliance with the regulatory requirements or where the standards were overly restrictive and cost-prohibitive. The Program also determined that several

necessary standards for accreditation were lacking. The final-form rulemaking amends various citations within the Scope of the regulations, but the applicable laws and acts within the Scope of the regulations remain unchanged.

Pursuant to section 4104(6) of the Act, the accreditation fees must be "in an amount sufficient to pay the department's cost of implementing and administering the accreditation program." In addition, 25 Pa. Code § 252.204(b) requires the Department to recommend to the Board regulatory changes to the accreditation fees every three years to address any disparity between the program income generated by the fees and program costs. In accordance with this requirement, the Program compared the work necessary to perform the functions of the Program to evaluate the costs associated with the Program. Based on this analysis, the Department determined that the accreditation fees contained in 25 Pa. Code § 252.204 are not sufficient to recover the Department's costs to implement to the program. These final-form regulations provide a new fee structure to cover the costs of the Laboratory Accreditation Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department, with the assistance of the LAAC, ensured that the interests, concerns, and needs of the regulated community were considered and implemented appropriately. The LAAC met throughout 2014, 2015, and 2016 to review and comment on drafts of the proposed and final-form Chapter 252 amendments presented by the Department. The Department also discussed the written comments received during the public comment period during a meeting of the LAAC on December 7, 2016. On December 7, 2016, the LAAC unanimously voted to recommend the final-form Chapter 252 amendments for presentation to the Board.

E. *Summary of Changes to the Proposed Rulemaking*

Editorial corrections and amendments were made throughout the final-form rulemaking based on comments received during the public comment period to ensure that the final-form rulemaking meets the requirements of the *Pennsylvania Code & Bulletin Style Manual*. For example, the term "but not limited to" was removed throughout.

Subchapter A.

§ 252.3. The applicable statutes for which environmental testing must be conducted by an accredited laboratory are amended to accurately reflect the correct names and citations.

Subchapter B.

§§ 252.201 & 252. 203. In the final-form rulemaking, the terms "on forms provided by the Department" were added in response to a comment by the Independent Regulatory Review Commission (IRRC) concerning the format and content of the application requirements that environmental laboratories must submit. The final-form rulemaking adds additional language to § 252.203(d) at the suggestion of IRRC to add clarity to the written client notification requirements for laboratories when the laboratory's accreditation certificate expires.

Laboratories are required to notify all affected customers of the loss or lapse in accreditation in writing within 48 hours of the certificate expiration. This additional language explains that the Department may choose to require the use of specific language or to require Department approval of the notice before issuance.

Subchapter C.

§ 252.304. The requirement for laboratory personnel to meet any more stringent qualification requirements established by method, regulation, or program was added as subsection (a)(4) in response to comments received during the public comment period. The proposed rulemaking included this provision in the laboratory supervisor qualifications section, but, as noted by two commentators, this provision is also applicable to some laboratory personnel.

§ 252.306. The allowance for re-certification of expired standards, reagents and media in § 252.306(h)(6) was removed in the final-form rulemaking based on a comment received from the public. The Department added this provision in 2010, but no laboratory has sought approval from the Department for approval to re-certify expired laboratory materials, thus removal of this provision does not negatively impact the regulated community and will ensure that laboratories use valid standards.

At the suggestion of several public comments, the provision for temperature distribution studies for microbiology incubators in § 252.306(j) was amended to exempt this requirement for circulating water baths. Circulating water baths ensure even temperature distribution throughout the incubator. Distribution studies are not necessary to ensure valid temperature distribution throughout the unit.

§ 252.307. At the suggestion of a commentator, the Department removed the requirement for the laboratory to develop the sample collection and preservation documents from § 252.307(j). The Department does not intend to require a laboratory to develop procedures that might already exist or be available from other organizations provided that the sample collection and preservation instructions meet the requirements of subsections (f) and (g).

Subchapter D.

§ 252.401. Significant public comment and discussion during public meetings of the LAAC resulted in the addition to § 252.401(f) requiring that environmental laboratories check and document the pH of every sample container received by the laboratory. Numerous comments and concerns were raised regarding the proposed language, the necessity of the requirements, and the overall cost to the regulated community. After much discussion and consideration, the final-form rulemaking requires that the laboratory check the pH of each sample container for safe drinking water act compliance samples and whole effluent toxicity samples that are not collected by trained, accredited laboratory staff. The Safe Drinking Water Program and the United States Environmental Protection Agency's (EPA) Office of Water consider an improperly preserved sample invalid for compliance purposes. Therefore, unless each sample container used for sample analysis is verified to be at the correct pH, it is not possible to determine if the sample is valid and appropriately collected. This compromise ensures protection of the public health for

drinking water compliance samples but does not place an undue burden, financial or otherwise, on the regulated community testing non-drinking water samples.

§ 252.404. The final-form rulemaking adds necessary clarification to § 252.404(g)(2) to more thoroughly explain that a re-useable membrane filtration funnel must be checked for sterility with a sterility blank after every ten filtrations of a sample aliquot, not after every ten samples. A sample could include numerous dilutions and aliquots. Based on comments received, the Department removed the proposed addition to § 252.404(h)(4) and (5) to allow for the re-certification of expired positive and negative culture controls. As suggested by a commentator, the Department added a provision, § 252.404(h)(7), in the final-form rulemaking to ensure that positive and negative controls are processed under the same conditions as routine environmental samples. The proposed rulemaking added the statement "Department approved" to § 252.404(h)(5) with the intention to require the laboratories to obtain approval for their documented procedures for maintaining culture controls. This statement was determined to be unnecessary because the current regulation outlines the specific requirements for maintaining culture controls. Therefore, the additional language proposed by the Department was removed in this final-form rulemaking.

Subchapter F.

§ 252.601. Subsection (h) was amended in the final-form rulemaking in response to a comment from IRRC regarding the Department's requirements for corrective action based on deficiencies found during an assessment conducted by the Program. The final-form rulemaking clarifies that unless otherwise required or approved by the Department, environmental laboratories shall correct all deficiencies within 120 calendar days of receipt of the assessment report. Assessments occur for various reasons, including on-site assessments, review of a laboratory's request to add fields of accreditation, change in ownership and laboratory supervisor notices, etc. Laboratories are required to perform corrective actions and submit any requested evidence of correction to the Program to demonstrate compliance with the regulation. Subsection (h) clarifies that the Program can require the laboratory to correct the violation sooner than 120 days or can grant the laboratory additional time for correction based on the provisions of subsection (i).

Subchapter G.

§§ 252.702, 252.703 and 252.704. The final-form rulemaking adds additional language to §§ 252.702(d), 252.703(e), and 252.704(c) at the suggestion of IRRC to add clarity to the written client notification requirements for laboratories when a voluntary relinquishment, loss, or lapse in accreditation occurs. Laboratories are required to notify all affected customers of the loss or lapse in accreditation in writing within 72 hours of the change in accreditation status. This additional language explains that the Department may choose to require the use of specific language or to require Department approval of the notice before issuance.

§ 252.706. Based on public comment, the final-form rulemaking removes the signature requirement from subsection (c) to state that the name or initials must be included on the records. Subsection (b)(5) was corrected to note that the results of chemical "or" thermal preservation

verifications or adjustments, or both must be documented. The final-form rulemaking more clearly explains the Department's requirements for historical reconstruction of laboratory activities in subsection (c)(2) when making changes to records. Specifically, the laboratory is expected to document the rationale for any non-typographical correction to records.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

The Board approved publication of the proposed rulemaking at its May 17, 2016 meeting. The proposed rulemaking was published at 46 Pa.B. 5088 on August 20, 2016, with a 30-day public comment period. Comments were received from ten commentators, including IRRC.

The majority of the comments received during the public comment period related to requirements for microbiology incubation units, laboratory supervisor qualifications, sample acceptance and sample receipt, expired materials, and a general request for technical guidance documents from the Department to describe and detail compliance options with the new requirements.

Several commentators noted that the Department's proposal to require temperature distribution studies for incubation units used for microbiology testing should be amended. These commentators noted that circulating water baths are equitably distributed by design and should be exempt from the distribution study. The Department agreed with these comments and added language to the final-form rulemaking to exempt circulating water baths from the temperature distribution study.

Commentators stated that it would be helpful to have the Department develop technical guidance for how the Department would recommend compliance with the requirements for microbiology incubators detailed in the proposed rulemaking. The Department plans to develop technical guidance documentation in collaboration with the LAAC. These technical guidance documents will provide more detailed examples and options for how a laboratory might achieve compliance with the regulatory requirements for microbiology incubators regarding temperature distribution studies and the daily temperature monitoring requirements.

Several commentators provided comment regarding the Department's proposal to amend the laboratory supervisor qualification requirements. Some of the commentators expressed concern that the proposed reduction in years of experience for inorganic non-metals, basic water and wastewater, and basic microbiology might weaken the quality of results generated by accredited laboratories. Other commentators expressed support of the Department's proposal and suggested that it will be easier to find qualified laboratory supervisors with the reduction in years of experience. One commentator suggested that the Department should not reduce the years of experience, but should increase the years of experience and minimum number of college semester credit hours for all areas of supervision. The Department carefully considered these comments and determined that the language should remain the same in the final-form rulemaking regarding the qualifications for a laboratory supervisor. The methodologies and analytical technologies contained within the inorganic non-metals, basic microbiology, and basic drinking water and wastewater areas of testing are less complicated and more easily mastered. One year of experience in these areas should be sufficient to obtain mastery in these technical

disciplines and will also enable smaller laboratories to more easily comply with the accreditation regulations, thus reducing the burden on small businesses and publicly owned laboratories. The Department's requirements for laboratory supervisor experience and education for the other areas of laboratory testing, organics, trace metals, and complex microbiology are similar to those established by the National Environmental Laboratory Accreditation Program (NELAP) and the requirements of the final-form rulemaking are adequate to ensure proper experience and education of a laboratory supervisor.

Several commentators expressed concern that the Department's proposal to require that at least four of the minimum required college semester credit hours in biology must be microbiology credits for a microbiology laboratory supervisor is too stringent and not necessary. During meetings of the LAAC, several members of the public in attendance as well as the LAAC members requested that the Department require, that in addition to four credits in microbiology, all laboratory supervisors must have taken a microbiology laboratory course. After consideration of the public comments and after further discussion with the LAAC, the Department determined that requiring four credits of microbiology and not specifically requiring a laboratory course work is an acceptable compromise. Colleges and universities have many courses available online, and four microbiology credits can be obtained in a single course. An individual that proposes to supervise a microbiology laboratory needs the microbiology education obtained during a college-level microbiology course and four credits in microbiology. The techniques and methods included in the basic microbiology category are not limited to Colilert testing, as noted by several commentators. The basic microbiology category includes technologies such as membrane filtration, multiple tube fermentation, and pour plate. These techniques require understanding and proficiency with sterile techniques, positive and negative controls, and specific media preparation and uses. The Department did not make any changes in the microbiology supervisor sections from proposed rulemaking to final-form rulemaking.

Several commentators provided suggestions related to the Department's proposal to require chemical preservation checks of all sample bottles received by the laboratory. The Department had included this provision at the recommendation of the Safe Drinking Water (SDW) Program and the EPA's instruction that an improperly collected sample is invalid and cannot be used for compliance purposes. Through discussions with the regulated community, the Department decided to limit the pH testing requirement to those samples that require a specific pH by method, regulation, or permit, and all SDW compliance samples. This compromise will ensure the protection of the public health but reduce the financial burden for non-drinking water samples. The regulated community participating in the public meeting were amenable to the compromise. The Department also plans to develop technical guidance documents in collaboration with the LAAC to assist the regulated community in understanding the various options available to comply with the sample acceptance and handling requirements of the regulation.

Commentators also stated that the laboratory should not be required to develop sample handling, collection, and preservation instructions if adequate documentation for these activities already exist. The Department agreed with these commentators and amended the final-form rulemaking to clarify that the laboratory must maintain documentation of sample collection and preservation

requirements. The laboratory may choose to develop their own or use currently published materials from another source.

Finally, one commentator asserted that the proposed language to segregate expired chemicals from unexpired chemicals should not be accepted and expired chemicals should be removed from the laboratory and discarded. The commentator also stated that the Department's allowance for re-certification of expired chemicals, materials, and positive and negative controls should be removed from §§ 252.404(h) and 306(h) because the use of expired materials does not improve the quality of the testing results. The proposed language for segregation of expired chemicals was a compromise made between the Department and the LAAC to allow laboratories to maintain expired chemicals for non-compliance purposes but to ensure that they could not be mistaken as acceptable for use for compliance testing. However, the Department agreed with the suggestion to remove the allowance for re-certification of expired materials and removed this provision from the final-form rulemaking.

G. *Benefits, Costs, and Compliance*

Benefits

The most significant benefit of this final-form rulemaking is a clear, concise, and improved regulation for the regulated community. The final-form rulemaking will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories. All laboratories, particularly small laboratories, will benefit from allowing a laboratory supervisor to be absent for up to 21 days, rather than the current 16 days, and be replaced by a qualified staff member without requiring written notification to the Department. Several of the laboratory supervisor areas of experience qualifications were reduced from two years to one year. The final-form rulemaking removes the requirement for the Department to conduct "on-site" assessments, thus allowing the Department to explore and employ advances in technology to perform off-site assessments which can substantially reduce overall costs to the Program and the regulated laboratories.

The regulation also adds some specific requirements for NELAP laboratories. The current TNI (the NELAC Institute) Standard, which the NELAP laboratories must meet, is silent or lacking in specific requirements for several necessary standards. Requiring that all NELAP laboratories adhere to these regulations and amendments will ensure that all laboratories performing testing or analysis of compliance samples for the Department are meeting the same minimum standard.

Improved data quality will allow the Department, the regulated community, and the citizens of the Commonwealth to make better and more informed decisions concerning the protection of the environment and the protection of public health, safety, and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws which are covered by the regulations.

Compliance Costs

The direct costs of the final-form rulemaking is the payment of the accreditation fees. The Act requires that the fees be set in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit, such as large commercial laboratories and NELAP laboratories, will pay a higher accreditation fee.

The renewal fee for State accreditation is increased by $200 per year while the renewal fee for NELAP applicants is increased by $750 per year. The renewal application fees increase for all laboratories at a rate of approximately 30%. Each laboratory is also responsible for paying the appropriate category fee associated with its requested scope of accreditation, such as microbiology, trace metals, volatile organics, etc. The total accreditation fee for each laboratory is the renewal application fee plus each appropriate category fee. Each category fee was increased by between $100-200 depending on the complexity of each category. The fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation.

The final-form rulemaking includes a fee structure that is responsive to the needs of small laboratories. Specifically, increased accreditation costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories increase by $300. The current annual fee paid by these environmental laboratories is $1250.00, and the fee change will result in an annual fee of $1550.00. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. In addition, the fee structure includes changes including separation of the microbiology category into "basic" and "complex" to ensure that laboratories that are performing the more complex testing, which requires additional staff time and oversight, cover the costs of the accreditation. There were no public comments expressing objections to these increased fees.

Indirect costs will be related to the individual laboratory's implementation of the new requirements. Many in the regulated community are already in compliance with the additional requirements itemized in the final-form rulemaking and will not incur any additional costs for implementation. Others will be required to update or develop standard operating procedures and update recordkeeping procedures.

Cost savings will occur in the regulated community because the new and clarified requirements will enable laboratories to better understand the applicable requirements and should reduce the number of violations found during assessments, thus reducing the amount of time and money necessary to correct these violations.

Compliance Assistance Plan

Aside from the fee changes, the major changes that might require additional compliance assistance include the new requirements for sample collection instructions, sample receipt documentation, and microbiology incubator temperature distribution studies. The Department

plans to develop technical guidance in collaboration with the LAAC and the public. The other changes included within the final-form rulemaking are minor and in most cases clarify existing requirements or make current requirements less stringent. As such, the Department does not believe that a compliance assistance plan tailored to these changes is necessary. However, the Department will continue its ongoing compliance assistance efforts with mass email, updates to the website, and other activities.

The ultimate goal of the compliance assistance effort will be improving an environmental laboratory's ability to produce valid and defensible data for use by the Department, the regulated community, and the public. Several areas where compliance assistance is necessary are general laboratory operation, correct performance of specific test procedures, and documentation of laboratory activities. Compliance assistance in these areas has been made available to all environmental laboratories, regardless of size, throughout the Commonwealth.

Paperwork Requirements

The final-form rulemaking does not include any additional forms, reports, or other paperwork to be submitted.

H. *Pollution Prevention*

Not applicable.

I. *Sunset Review*

The Board is not establishing a sunset date for these regulations, since they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.

J. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 29, 2016, the Department submitted a copy of the notice of proposed rulemaking, published at 46 Pa.B. 5088, to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on DATE, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on DATE and approved the final-form rulemaking.

K. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) This final-form rulemaking does not enlarge the purpose of the proposed rulemaking published at 46 Pa.B. 5088 (August 20, 2016).

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

L. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapter 252, are amended by amending §§ 252.1, 252.3, 252.4-252.6, 252.201, 252.203-252.206, 252.301, 252.302, 252.304, 252.306, 252.307, 252.401, 252.402, 252.404, 252.501, 252.601, 252.701-252.706, 252.708 to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin.*

PATRICK MCDONNELL
Acting Chairperson

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VI. GENERAL HEALTH AND SAFETY

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

§ 252.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

NELAP accreditation body—An accreditation body that has been recognized as meeting the requirements of the NELAC Standard or the TNI Standard and has the authority to grant NELAP **[or TNI]** accreditation.

* * * * *

§ 252.3. Scope.

(a) *Environmental statutes.* This chapter applies to facilities that test or analyze environmental samples in the matrices listed in subsection (b) for the purpose of complying with the following environmental statutes:

(1) 58 Pa.C.S. Chapter 32 (relating to oil and gas development).

(2) The Clean Streams Law (35 P. S. §§ 691.1—691.1001).

(3) The Hazardous Sites Cleanup Act (35 P. S. §§ 6020.101—6020.1305).

(4) The Land Recycling and Environmental Remediation Standards Act (35 P. S. §§ 6026.101—6026.908).

(5) The Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1—721.17).

(6) The Solid Waste Management Act (35 P. S. §§ 6018.101—6018.1003).

(7) The Storage Tank and Spill Prevention Act (35 P. S. §§ 6021.101—6021.2104).

(8) The ~~Pennsylvania~~ Bituminous Coal Mine **SAFETY** Act (52 P. S. §§ ~~701-101—701-706~~ **690.101—690.708**).

(9) The Surface Mining Conservation and Reclamation Act (52 P. S. §§ 1396.1—~~1369.31~~ **1396.19a**).

(10) The Coal Refuse Disposal Control Act (52 P. S. §§ 30.51—~~30.206~~ **30.66**).

(11) The Bituminous Mine Subsidence and Land Conservation Act (52 P. S. §§ 1406.1—1406.21).

(12) The Noncoal Surface Mining Conservation and Reclamation Act (52 P. S. §§ 3001—3326).

§ 252.4. General requirements.

(a) Testing or analysis of environmental samples within a matrix identified in § 252.3 (relating to scope) and to comply with a statute listed in § 252.3 shall be performed by an environmental laboratory accredited under this chapter.

(b) An environmental laboratory testing **[or],** analyzing **or reporting results for** environmental samples in a matrix identified in § 252.3 and required by a statute identified in § 252.3 shall be accredited and in compliance with this chapter to generate data and perform analysis used to comply with an environmental statute listed in § 252.3.

§ 252.5. NELAP**[/TNI]** equivalency.

(a) An environmental laboratory may apply to the Department for NELAP accreditation for the fields of accreditation for which the Department offers accreditation.

(b) An environmental laboratory seeking NELAP accreditation shall:

(1) Submit a complete application as provided in Subchapter B (relating to application, fees and supporting documents).

(2) Comply with Subchapter E (relating to proficiency test study requirements).

(3) Comply with Subchapter F (relating to **[onsite]** assessment requirements).

(4) Comply with Subchapter G (relating to miscellaneous provisions).

(5) Comply with the current edition of the NELAC Standard or TNI Standard.

(6) Comply with § 252.307 (relating to methodology).

(7) Comply with § 252.401 (relating to basic requirements).

(c) An environmental laboratory receiving NELAP accreditation from the Department may apply for accreditation under the remainder of this chapter for the fields of accreditation that are not included in NELAP accreditation and for which the Department offers accreditation.

(d) An environmental laboratory receiving NELAP accreditation from the Department may only test or analyze environmental samples within the fields of accreditation authorized by the accreditation received from the Department.

§ 252.6. Accreditation-by-rule.

(a) *Purpose.* Environmental laboratories performing testing or analysis **or reporting results** described in this section will be deemed to have accreditation-by-rule if the following general requirements are met:

* * * * *

(6) The environmental laboratory is reporting **only** the results of the testing or analysis of environmental samples **specified in subsections (c) and (f)** in conformance with the applicable State or Federal laws, regulations, orders or permit conditions.

* * * * *

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.201. Application and supporting documents.

(a) An environmental laboratory seeking accreditation for one or more fields of accreditation within a matrix described in § 252.3 (relating to scope) or that seeks to add a field of accreditation**[**,**]** shall apply to the Department for accreditation ~~in~~ **[writing on forms provided] ON FORMS PROVIDED BY THE DEPARTMENT AND IN the format specified** by the Department. The applicant shall provide other relevant material requested by the Department.

* * * * *

§ 252.203. Accreditation renewal.

(a) Applications for accreditation renewal shall be submitted annually to the Department at least 60 calendar days prior to the expiration date of the current certificate of accreditation **[on forms provided] IN WRITING ON FORMS PROVIDED BY THE DEPARTMENT AND in the format specified** by the Department.

(b) An application for accreditation renewal must include the appropriate application fee in accordance with § 252.204 (relating to fees).

(c) Failure to submit an application for renewal in accordance with this section will result in a lapse in accreditation if the Department has not approved the renewal application prior to the

expiration of the current certificate of accreditation. If a lapse in accreditation occurs, the environmental laboratory shall cease all testing or analysis of environmental samples for the affected fields of accreditation.

(d) Within 48 hours of expiration of the certificate of accreditation, the laboratory shall notify each of its customers affected by the expiration of the certificate of accreditation in writing of the lapse in accreditation ~~in a manner approved by the Department~~. THE DEPARTMENT MAY CHOOSE TO REQUIRE THE LABORATORY TO USE SPECIFIC LANGUAGE IN THE WRITTEN NOTICE OR TO REQUIRE DEPARTMENT APPROVAL OF THE NOTICE BEFORE ISSUANCE.

§ 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, change of ownership, change in administrative information, addition of fields of accreditation**[,]** or supplemental onsite assessment. A check must be payable to "Commonwealth of Pennsylvania." **When the Department is able to accept credit card payments, an environmental laboratory may make payment by credit card and shall pay to the Commonwealth all service charges or other administrative fees in addition to the accreditation fees.** The fees are as follows:

Category	Fee	
~~Aplication~~ **APPLICATION** fee—Initial Application for State Accreditation	**[$750]**	**$1,500**
Application fee—Renewal Application for State Accreditation	**[$500]**	**$700**
Application fee—Ownership Transfer or Change in Administrative Information	$150	
Application fee—Initial Application for NELAP**[/TNI]** Accreditation	**[$2,500]**	**$3,500**
Application fee—Renewal Application for NELAP**[/TNI]** Accreditation	**[$2,000]**	**$2,750**
Application fee—Addition of Field of Accreditation	**[$250]**	**$350**
Application fee—Supplemental Onsite Assessment	$500	
Basic Drinking Water Category—Includes one method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E-coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	**[$650]**	**$750**
Basic Nonpotable Water Category—Includes one method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and one method for each type of residue including % Solids for land applied biosolids	**[$750]**	**$850**
Asbestos—first matrix	**[$400]**	**$600**
Basic Microbiology—**includes fecal coliform, total coliform, *E. coli* and heterotrophic bacteria**—first matrix	**[$500]**	**$700**
Complex Microbiology—first matrix		**$1,000**
Trace Metal Category—first matrix	**[$550]**	**$750**
Inorganic Nonmetal Category—first matrix	**[$600]**	**$850**
Purgeable Volatile Organic Chemicals—first matrix	**[$650]**	**$850**

Extractable and Semivolatile Organic Chemicals—first matrix	**[$1,500]**	**$1,750**
Dioxin—first matrix	**[$650]**	**$850**
Radiochemical Category—first matrix	**[$750]**	**$950**
Whole Effluent Toxicity Testing—first matrix	**[$700]**	**$950**
Asbestos—second matrix	**[$350]**	**$450**
Basic Microbiology—**includes fecal coliform, total coliform, *E. coli* and heterotrophic bacteria**—second matrix	**[$450]**	**$600**
Complex Microbiology—second matrix		**$900**
Trace Metal Category—second matrix	**[$500]**	**$600**
Inorganic Nonmetal Category—second matrix	**[$550]**	**$700**
Purgeable Volatile Organic Chemicals—second matrix	**[$600]**	**$700**
Extractable and Semivolatile Organic Chemicals—second matrix	**[$1,400]**	**$1,600**
Dioxin—second matrix	**[$600]**	**$700**
Radiochemical Category—second matrix	**[$700]**	**$850**
Asbestos—third matrix	**[$300]**	**$400**
Basic Microbiology—**includes fecal coliform, total coliform, *E. coli* and heterotrophic bacteria**—third matrix	**[$400]**	**$500**
Complex Microbiology—third matrix		**$800**
Trace Metal Category—third matrix	**[$450]**	**$550**
Inorganic Nonmetal Category—third matrix	**[$500]**	**$650**
Purgeable Volatile Organic Chemicals—third matrix	**[$550]**	**$600**
Extractable and Semivolatile Organic Chemicals—third matrix	**[$1,300]**	**$1,450**
Dioxin—third matrix	**[$550]**	**$650**
Radiochemical Category—third matrix	**[$650]**	**$750**

* * * * *

§ 252.205. Out-of-State laboratories.

(a) Out-of-State environmental laboratories may apply for primary accreditation or secondary accreditation from the Department.

(1) *Primary accreditation.* Out-of-State environmental laboratories may apply to the Department for primary accreditation under this chapter.

(2) *Secondary accreditation.*

(i) The Department will recognize accreditation granted by a primary NELAP**[/TNI]** accreditation body for the same fields of accreditation for which the Department is a primary NELAP**[/TNI]** accreditation body **provided the environmental laboratory meets the requirements of § 252.5 (relating to NELAP equivalency).**

* * * * *

§ 252.206. Out-of-State onsite reimbursement.

In addition to the nonrefundable application fee, an out-of-State environmental laboratory shall reimburse the Department for the following costs associated with onsite assessments necessitated by accreditation:

(1) Transportation costs, including airfare, mileage, tolls, car rental, public transportation and parking.

(2) Meals and lodging.

(3) Travel time for each assessor at a rate of **[$50/hour] $75/hour**.

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

* * * * *

(h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor **and who is approved by the Department as described in subsection (a)** to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding **[16] 21** consecutive calendar days. If this temporary absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

* * * * *

§ 252.302. Qualifications of the laboratory supervisor.

(a) A laboratory supervisor of an environmental laboratory engaged in chemical analysis **of organics or metals, or both,** shall have the following qualifications:

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least 24-college semester credit hours in chemistry.

(3) At least 2 years of experience in the testing or analysis of environmental samples in representative inorganic and organic fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. An earned master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(b) A laboratory supervisor of an environmental laboratory **[limited to] engaged in** inorganic

nonmetals chemical analysis**[, other than metals analysis,]** shall have the following qualifications:

(1) At least an earned associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering, or 2 years of equivalent and successful college education.

(2) At least 16-college semester credit hours in chemistry.

(3) At least **[2 years] 1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(c) A laboratory supervisor of an environmental laboratory engaged in microbiological or biological analysis shall have the following qualifications:

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least 16-college semester credit hours in **[general microbiology or]** biology. **At least 4 of the 16-college semester credit hours must be in microbiology.**

(3) At least 2 years of experience in the testing or analysis of environmental samples in representative microbiological or biological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. A master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(d) A laboratory supervisor of an environmental laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, ***E. coli*** and heterotrophic bacteria shall have the following qualifications:

(1) At least an associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) A minimum of 4-college semester credit hours in **[biology] microbiology**.

(3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in **[biology] microbiology** may be substituted for the associate's degree.

(4) At least **[2 years] 1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(e) A laboratory supervisor of an environmental laboratory engaged in radiological analysis shall have the following qualifications:

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least 24-college semester credit hours in chemistry **or health physics**.

(3) At least 2 years of experience in the testing or analysis of environmental samples in representative radiological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. An earned master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(f) A laboratory supervisor of an environmental laboratory engaged in microscopic examination of asbestos or airborne fibers shall have the following qualifications:

(1) For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of formal course work in the use of the instrument**[,]** and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.

(2) For procedures requiring the use of a polarized light microscope, an associate's degree or 2 years of college study, successful completion of formal coursework in polarized light microscopy**[,]** and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.

(3) For procedures requiring the use of a phase contrast microscope, an associate's degree or 1 year of college study, documentation of successful completion of formal coursework in phase contrast microscopy**[,]** and 1 year of experience, under supervision, in the use of the instrument.

(g) Notwithstanding any other provision of this section, a laboratory supervisor of an environmental laboratory limited to the basic nonpotable water category or the basic drinking water category**[,]** shall have the following qualifications:

(1) At least 16-college semester credit hours in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least **[2 years] 1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(h) Notwithstanding any other provision of this section, an employee of a drinking water, wastewater or industrial waste treatment facility meeting the following requirements will be deemed qualified as a laboratory supervisor of an environmental laboratory:

(1) The employee holds a valid treatment plant operator's certificate under the Water and Wastewater Systems Operators' Certification Act (63 P.S. §§ 1001—1015.1) in the appropriate water or wastewater subclassification for the facility.

(2) The employee holds a valid certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification.

(3) **[Until 12 months after a certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification becomes available from the Department, 2 years of experience performing testing or analysis of environmental samples using the methods and procedures currently in use by the environmental laboratory may be substituted for a laboratory supervisory certificate.] At least 1 year of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or maintain accreditation.**

(i) Approval as a laboratory supervisor under subsection (h) will be limited to the fields of accreditation required by the scope of that facility's regulatory permit.

(j) A laboratory supervisor of an environmental laboratory engaged in whole effluent toxicity analysis shall have the following qualifications:

(1) At least an associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) A minimum of 4-college semester credit hours in biology.

(3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in biology may be substituted for the associate's degree.

(4) At least 2 years of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(k) College semester credit hours shall be obtained from an accredited college or university recognized by the United States Department of Education.

(l) Foreign transcripts must be translated into English and evaluated for United States semester credit hour equivalency by a credential evaluation agency accredited by the National Association of Credentials Evaluation Services or a Department of Education approved agency.

(m) If a method, regulation or program requires more stringent qualifications for education or experience, or both, the laboratory shall meet the more stringent requirement.

§ 252.304. Personnel requirements.

(a) General requirements for technical staff.

(1) An environmental laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

* * * * *

(4) IF A METHOD, REGULATION OR PROGRAM REQUIRES MORE STRINGENT QUALIFICATIONS FOR EDUCATION OR EXPERIENCE, OR BOTH, THE LABORATORY TECHNICAL STAFF SHALL MEET THE MORE STRINGENT REQUIREMENT.

(b) *Laboratory management responsibilities.* The environmental laboratory management shall be responsible for:

* * * * *

(3) Ensuring and documenting that the training and competency of each member of the environmental laboratory technical staff is kept up to date by maintaining records demonstrating the following:

* * * * *

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities has been performed. The initial demonstration of capability requirements are as follows:

* * * * *

(D) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed; otherwise, an initial demonstration of capability shall be performed as follows:

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be **[approximately ten times the detection limit] in the lower half of the calibration range or at or below the maximum contaminant level for Safe Drinking Water Act compliance testing, whichever is lower.**

(II) At least four aliquots of the quality control sample shall be prepared and analyzed **consecutively** according to the method. **The preparation or analysis, or both, may occur on a single day or over the course of multiple days.**

(III) Using all of the results, calculate **the individual recovery,** the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(IV) Compare the information from subclause (III) to the corresponding acceptance criteria for precision and accuracy in the method. **If the method or regulation does not specify acceptance limits, the % Relative Standard Deviation must be less than 20%.** To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

* * * * *

(vii) A demonstration of continued proficiency by at least one of the following every 12 months for each method that relates to the employee's job responsibilities:

* * * * *

(D) At least four consecutive laboratory control samples with acceptable levels of precision and accuracy **as required by the initial demonstration of capability described in subparagraph (vi)**.

* * * * *

§ 252.306. Equipment, supplies and reference materials.

* * * * *

(c) An environmental laboratory shall assure that the test instruments **and all equipment, supplies and reference materials** consistently operate within **and meet** the specifications required of the application for which **[the equipment] it** is used.

* * * * *

(f) The following pieces of equipment shall be maintained according to this subsection.

* * * * *

(4) *Analytical or pan balances.*

* * * * *

(v) An environmental laboratory shall maintain records in a laboratory notebook of balance calibrations **and verifications** that document the balance identification, date of calibration**, date of** verification, reference weights used**, observed measurement** and initials of the individual performing the calibration **verification**.

* * * * *

(5) *pH meter.*

* * * * *

(iii) The pH meter shall be calibrated daily or before each use, whichever is less frequent, by one of the following:

(A) With at least three standard buffers which are at least three pH units apart **[and which bracket the expected pH range of the samples]**.

* * * * *

(v) Records of pH meter calibration shall be maintained in a laboratory notebook that document the date of calibration, calibration buffers used**, results of the calibration, results of the calibration verification** and initials of the individual conducting the calibration.

* * * * *

(7) *Refrigeration equipment and freezers.*

* * * * *

(ii) Calibration-corrected temperatures for each refrigerator and freezer shall be recorded once a day for each **working** day in use for all laboratory activities. The date, refrigerator or freezer identification, calibration corrected temperature and initial of responsible individual shall be recorded.

* * * * *

(8) *Incubators, water baths, heating blocks and ovens.*

* * * * *

(iv) Calibration-corrected temperatures for each incubator, water bath, heating block or oven shall be recorded once a day for each **working** day in use for all laboratory activities. When used as an incubation unit for microbiology, the calibration-corrected temperature shall be recorded at least twice per day **each day the incubator is** in use with the readings separated by at least 4 hours. The incubator, water bath, heating block or oven identification, date, time, calibration corrected temperature and the initials of the responsible individual shall be recorded.

(9) *Volumetric dispensing devices.*

(i) Except for Class A glassware **and glass microliter syringes, [mechanical]** volumetric dispensing devices**,** including**~~, but not limited to,~~ graduated cylinders, pipettes and** burettes**[,**

autopipetors and dilutors], must be of sufficient sensitivity for the application **and the environmental laboratory shall verify and document the accuracy of the volume of use for each lot or at least once per year, whichever is more frequent.** Delivery volumes of mechanical volumetric dispensing devices **such as mechanical pipettes, autopipetors and dilutors** shall be checked at least once every 3 months.

* * * * *

(10) *Graduated sample containers.*

(i) Except for Class A glassware, when graduation marks on filter funnels, sample bottles or labware are used to measure sample volume **or prepare standards or reagents**, an environmental laboratory shall verify and document the accuracy of the volume of use for each lot or at least once per year, whichever is more frequent.

* * * * *

(g) An environmental laboratory shall maintain records for all reference materials, reagents, **laboratory supplies that are essential to obtain analytical results** and support services utilized by the laboratory for testing or analysis.

(h) Reference materials, reagents, media and laboratory supplies that are essential to obtain analytical results (such as filters, solid-phase extraction disks/cartridges, presterilized filtration units, certified precleaned laboratory supplies, disposable volumetric equipment, prepreserved sample containers) must meet the following minimum requirements:

* * * * *

(2) Standard, reagent**, media** and laboratory supply receipt records shall be maintained. These records must include vendor, lot number, amount received, date of receipt, expiration date and certificates of analysis or purity, if available.

* * * * *

(4) An environmental laboratory shall maintain records of standard, reagent and media preparation. Standard**, media** and reagent preparation records must contain identification of the compound, manufacturer, lot number, concentration, amount prepared, date prepared, final pH if used for microbiology testing, initials of the individual preparing the solution and expiration date.

(5) Reagent**, media** and standard solution containers shall be labeled with identification of the compound, traceability to the preparation record, such as unique identifier, and expiration date.

(6) Standards, reagents and media may not be used past the date of expiration ~~**unless reevaluated and validated by a procedure approved by the Department prior to use**~~**. Expired reagents, standards and media shall be segregated from unexpired laboratory**

materials in a manner that ensures they are not used for the testing of environmental samples.

(7) **[Reagent and standard solutions] Reagents, standards and media** shall be checked regularly for signs of decomposition and evaporation. **[Reagent and standard solutions] Reagents, standards and media** exhibiting signs of decomposition or evaporation shall be discarded.

(8) When reagents**, standards and media** are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(9) Compressed gases must be of commercial grade, unless a method specifies other requirements.

(i) Plastic and glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the method shall be documented in a laboratory standard operating procedure.

(j) EXCEPT FOR CIRCULATING WATER BATHS, THE ~~The~~ laboratory shall perform temperature distribution studies for incubators that are used as incubation units for microbiology.

(1) The laboratory shall perform a temperature distribution study for each incubator prior to first use, after repair and every 3 years by the following procedure:

(i) The laboratory shall develop a procedure to determine the temperature distribution and fluctuations within an incubator. The laboratory shall take into account the size of the incubator (height, width and depth), number of shelves and type of incubator when developing the procedure to perform the temperature distribution study.

(ii) At a minimum, the laboratory shall monitor and record the temperature of each shelf.

(iii) Incubators that do not maintain constant temperatures within the acceptable temperature range for the application may not be used. The laboratory may establish procedures to limit incubator use to specific shelves or areas of the incubator that can be verified to maintain acceptable temperature fluctuations.

§ 252.307. Methodology.

* * * * *

(i) When a method specifies a validation procedure, the validation procedure shall be completed before environmental samples may be analyzed and reported. The results of this validation procedure shall be documented and kept on file for the duration of use of the method and for at least 5 years after the method is no longer in use.

(j) An environmental laboratory shall ~~develop and~~ maintain instructions for sample collection and preservation that meet the requirements of subsections (f) and (g).

(1) The environmental laboratory's instructions must accurately reflect all aspects of the sample collection and preservation requirements for the particular analyses, including the following:

(i) Container type, size and number of containers or bottles.

(ii) Sample collection method, amount of sample required and explanation of other specific requirements for sample collection such as "zero headspace" and "first draw."

(iii) Chemical preservation, including type of preservation and the procedure used to preserve the sample.

(iv) Thermal preservation, including the temperature requirements and procedure used to preserve the sample.

(v) Field blank requirements.

(vi) Holding time.

(2) The environmental laboratory shall make the sample collection and preservation instructions available to all laboratory sample collection personnel and to customers and clients that collect samples.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

* * * * *

(f) An environmental laboratory shall establish procedures for handling environmental samples.

(1) The environmental laboratory shall implement procedures for checking **[the thermal or chemical, or both, preservation and the sample container] and verifying the condition of the sample**. The results of these checks shall be recorded. **The environmental laboratory shall check:**

(i) The sample container and the sample preservation, both thermal and chemical, of each sample.

(ii) The sample pH for all samples to be analyzed for ~~chemistry,~~ whole effluent toxicity and SAFE DRINKING WATER CHEMISTRY ~~radiochemistry~~ fields of accreditation, UNLESS THE SAMPLE IS COLLECTED BY THE ENVIRONMENTAL LABORATORY PERFORMING THE ANALYSIS.

(iii) The sample for the presence of residual chlorine when the presence of residual chlorine will compromise the validity of the test.

(2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:

(i) The client/project name.

(ii) The date, time and location of sample collection, name of sample collector and field identification code.

(iii) The date and time of laboratory receipt **and identification of the individual receiving the sample at the laboratory**.

* * * * *

(j) An environmental laboratory shall develop procedures for reporting results of testing or analysis of environmental samples. Each test report must include at least the following information, except as specified in subsection (k).

* * * * *

(8) The **date and** time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.

* * * * *

(15) An identification of subcontracted results.

(16) A unique test report identifier code, such as a serial number or other unique code.

(17) An identification of amendments to the test report. The laboratory shall uniquely identify all amendments to a test report. The amended report shall be issued in the form of a further document, data transfer or completely new test report, which includes the statement "Amended" or "Revised" and the identification of the unique laboratory code that meets the requirements of paragraph (16).

(k) Tests performed by an environmental laboratory operated by a facility that provides results to the facility management for compliance purposes do not need to be reported under subsection (j) regarding procedures for reporting results, provided the information required by subsection (j) is maintained under § 252.706.

* * * * *

(n) Policies, procedures, protocols and practices specified in this section must be in writing and be followed.

(o) The environmental laboratory shall clearly identify opinions and interpretations as opinions and interpretations on test reports. When test reports include opinions and interpretations, the laboratory shall include an explanation for the basis upon which the opinions and interpretations have been made.

§ 252.402. Essential quality control requirements—chemistry.

* * * * *

(c) Initial calibration requirements are as follows:

* * * * *

(4) Raw data records shall be retained to permit reconstruction of the initial calibration, **including~~, but not limited to,~~ identification or reference to the reagents, standards and supplies used, dates of analysis, instrument identification, results of the initial calibration, calibration criteria and analyst identification**.

* * * * *

(f) Calibration verification requirements are as follows:

* * * * *

(6) Acceptance criteria for calibration verification standards in the method shall be followed. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with *Standard Methods for the Examination of Water and Wastewater* (available from the American Public Health Association, 800 I Street, NW, Washington, D.C. 20001) to** determine internal criteria and document the procedure used to establish the acceptance limits.

(7) If a calibration verification standard fails the established acceptance criteria, an environmental laboratory shall initiate corrective actions. If the corrective actions fail to produce an immediate consecutive calibration verification standard within the acceptance criteria, a new calibration verification standard shall be prepared. If the freshly prepared calibration verification standard fails to produce a result within the established acceptance criteria, the environmental laboratory shall recalibrate the test or analysis according to the method or as set forth in subsection (c) and as set forth in either subsection (d) or (e).

(8) To the extent possible, and as provided by paragraph (1), environmental samples not bracketed by acceptable calibration verification standards shall be reanalyzed. If the calibration verification standard is found to be out of control, and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed calibration verification standard shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers. **[Sample results**

associated with an unacceptable calibration verification may be useable under the following conditions:

(i) When the acceptance criteria for the calibration verification are exceeded high and associated sample results are below the lowest level of quantitation for the analyte of interest.

(ii) When the acceptance criteria for the calibration verification are exceeded low and associated sample results are above the maximum regulatory limit for the analyte of interest.]

(g) Method blank requirements are as follows:

* * * * *

(5) If a contaminant is detected in the method blank, the source of contamination shall be investigated and measures shall be taken to minimize or eliminate the problem.

(6) Raw data records shall be retained to permit reconstruction of the method blank.

[(6)] (7) To the extent possible, any environmental samples associated with a contaminated method blank shall be reprocessed for analysis. If a contaminated method blank is found to be out of control, and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the contaminated method blank shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

(h) Laboratory control sample requirements are as follows:

* * * * *

(6) Each individual laboratory control sample **[must] shall** be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with *Standard Methods for the Examination of Water and Wastewater* (available from the American Public Health Association, 800 I Street, NW, Washington, D.C. 20001) to** determine internal criteria and document the procedure used to establish the limits.

(7) Raw data records shall be retained to permit reconstruction of the laboratory control sample.

[(7)] (8) Environmental samples associated with an out of control laboratory control sample **[must] shall** be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(i) Sample duplicate requirements are as follows:

* * * * *

(4) Each duplicate relative percent difference shall be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with *Standard Methods for the Examination of Water and Wastewater* (available from the American Public Health Association, 800 I Street, NW, Washington, D.C. 20001)to** determine internal criteria and document the procedure used to establish the acceptance limits.

* * * * *

(j) Surrogate spike requirements are as follows:

* * * * *

(3) The results of the surrogate spike shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for surrogate recovery in the method, the environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with *Standard Methods for the Examination of Water and Wastewater* (available from the American Public Health Association, 800 I Street, NW, Washington, D.C. 20001) to** establish internal criteria and document the method used to establish the acceptance limits.

* * * * *

§ 252.404. Essential quality control requirement—microbiology.

* * * * *

(c) The following pieces of equipment shall be maintained according to this subsection:

(1) *Autoclave.*

(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. **[Because of safety concerns and difficulties with operational control, pressure cookers should not be used.]** Pressure cookers may not be used **[for sterilization of media]**.

* * * * *

(9) *Plastic and glassware washing procedure.*

(i) Prior to the initial use of a lot of detergent or washing procedure, an environmental laboratory shall perform an inhibitory residue test utilizing the method described in the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from **the** American Public Health Association, **800 I Street, NW, Washington, D.C. 20001**). Records of inhibitory residue tests shall be maintained and include the detergent identification, date, calculations, results and initials of responsible individual.

(ii) Washed plastic and glassware shall be tested at least once each month for possible acid or alkaline residue by testing at least one piece of plastic and glassware with a suitable pH indicator such as 0.04% bromothymol blue. Records of pH tests shall be maintained **and include the date, results and identification of the responsible individual**.

* * * * *

(d) The requirements for reagent water are as follows:

* * * * *

(6) The bacteriological water quality test need not be performed if the environmental laboratory can supply documentation to show that their laboratory pure water or reagent water meets the criteria, as specified in section 1080 of the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from **the** American Public Health Association, **800 I Street, NW, Washington, D.C. 20001**), for Type I (high-quality) or Type II (medium-quality) reagent water.

(7) The heterotrophic plate count and bacteriological water quality test ratio analyses described in paragraphs (2) and (3) shall be performed by an environmental laboratory accredited under this chapter for the appropriate field of accreditation.

(e) The requirements for dilution/rinse water are as follows:

(1) Stock buffer solution or peptone water shall be prepared as specified in the currently approved editions of ~~the~~ **the** *Standard Methods for the Examination of Water and Wastewater* (available from **the** American Public Health Association, **800 I Street, NW, Washington, D.C. 20001**).

(2) Stock buffers shall be autoclaved or filter-sterilized. Stock buffers shall be refrigerated and must be free from turbidity.

(3) Dilution/rinse water solutions shall be prepared as specified in the currently approved editions of ~~the~~ *Standard Methods for the Examination of Water and Wastewater* (available from **the** American Public Health Association, **800 I Street, NW, Washington, D.C. 20001**).

(f) The requirements for media are as follows:

* * * * *

(4) After preparation, media shall be stored and maintained as follows:

* * * * *

(iv) Fermentation media stored in a refrigerator shall be **[incubated overnight at] brought to** room temperature before use. Media that shows growth or **[bubbles] false positive results** may not be used.

* * * * *

(g) An environmental laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization or environmental exposure as follows:

(1) A sterility blank shall be analyzed for each lot of preprepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date **and time of the start and end of incubation**, results and initials of **the** responsible **[individual] individuals**. If sterility blank indicates contamination, the media may not be used.

(i) For chromogenic/fluorogenic media, add single-strength media to sterile DI water and incubate at the appropriate temperature and time.

(ii) For all other media, incubate uninoculated, single-strength at the appropriate temperature and time.

(2) For each reusable membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning and at the end of the series. A series is considered ended when more than 30 minutes elapses between filtrations. The laboratory shall insert a sterility blank after every **[10] ten ~~samples~~ SAMPLE ALIQUOTS** filtered through each membrane **[filration] filtration** unit or sanitize filtration units by UV light after each sample filtration in addition to the regular rinsing procedure. Records of sterility blank results **[must] shall** be maintained **in the same manner as the associated sample and include the date and time of the start and end of the incubation, results and initials of the responsible individuals**. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.

(3) For presterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot.

(4) Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with an appropriate nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with an appropriate nonselective growth media. Results shall be maintained and include sample container identification, date **and time of the start and end of**

incubation, results and initials of responsible **[individual] individuals.** If sample container sterility check indicates contamination, the affected sample container may not be used.

(5) A sterility blank shall be performed on each batch of dilution/rinse water prepared in the laboratory and on each batch of preprepared, ready-to-use dilution water with an appropriate **[non-selective] nonselective** growth media. The concentration of media shall be single strength after addition of dilution water. Results shall be maintained and include dilution/rinse water identification, date **and time of the start and end of incubation**, results and initials of the responsible **[individual] individuals**. If dilution/rinse water sterility check indicates contamination, the affected dilution water may not be used.

(6) At least one filter from each new lot of membrane filters shall be checked for sterility with an appropriate nonselective growth media. Results shall be maintained and include membrane filter identification, date **and time of the start and end of incubation**, results and initials of the responsible **[individual] individuals**. If the membrane filter sterility check indicates contamination, the affected membrane filters may not be used.

(7) Sterility checks on Quanti-Tray™ sample trays shall be performed on at least one sample tray for each lot of purchased presterilized sample ~~tray~~ TRAYS with an appropriate nonselective growth media. Results shall be maintained and include sample tray identification, date and time of the start and end of incubation, results and initials of the responsible individuals. If the sample tray sterility check indicates contamination, the affected lot of sample trays may not be used.

(h) The requirements for positive and negative culture control checks are as follows:

(1) Each preprepared, ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested by the laboratory with at least one pure culture of a known positive reaction prior to first use of the medium. Records shall be maintained and include the date **and time of the start and end of incubation**, media lot or batch number, type of media, positive culture control organism identification, results and initials of **the** responsible **[individual] individuals**. If positive culture control checks do not meet expected results, the affected media may not be used.

(2) Each preprepared, ready-to-use lot of selective medium and each batch of selective medium prepared in the laboratory shall be tested by the laboratory with at least one pure culture of a known negative reaction prior to first use of the medium. Records shall be maintained and include the date **and time of the start and end of incubation**, media lot or batch number, type of media, negative culture control organism identification, results and initials of the responsible **[individual] individuals**. If negative culture control checks do not meet expected results, the affected media may not be used.

(3) An environmental laboratory shall use stock positive and negative culture controls that are known and traceable to a recognized National collection. Documentation of traceability shall be maintained.

(4) Stock positive and negative culture controls shall be discarded ~~upon~~ **AFTER** the manufacturer's expiration date ~~unless~~ **[it is shown through appropriate biochemical and purity tests]** ~~re-evaluated and validated by a procedure approved by the Department that demonstrates that the stock culture control has not been contaminated or altered~~.

(5) Culture controls may be single use or cultures maintained by the laboratory using a ~~Department approved and~~ documented procedure that maintains the purity and viability of the organisms.

(6) For cultures maintained by the laboratory, the following criteria must be met:

* * * * *

(7) POSITIVE AND NEGATIVE CONTROLS MUST BE PROCESSED UNDER THE SAME CONDITIONS AND USING THE SAME EQUIPMENT AS ROUTINE ENVIRONMENTAL SAMPLES, INCLUDING ALL STEPS OF THE PREPARATION AND ANALYTICAL PROCEDURE.

(i) For test methods that specify colony counts, duplicate counts shall be performed monthly on one positive sample for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more than 10%. In an environmental laboratory with only one analyst, the analyst shall count the same plate twice. Counts may not differ by more than 5%.

(j) Quality control checks, including~~, but not limited to,~~ sterility checks and positive and negative controls, shall be conducted after the laboratory receives the material or supply and before or during first use. These checks shall be performed by an environmental laboratory accredited under this chapter and utilizing the same supplies, reagents and media to be used during laboratory analysis of environmental samples. Certificates of Analysis from a manufacturer may not be used to demonstrate compliance with the requirements of this subsection.

[(j)] (k) Records of all equipment, reference materials, reagents, media and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

* * * * *

(o) An environmental laboratory shall evaluate and report the analytical result of each proficiency test study sample to the proficiency test reporting limit for each field of accreditation, when available, as outlined in subsection (a).

(p) The Department will invalidate a proficiency test study result that is not handled, managed, analyzed or reported in accordance with this section.

Subchapter F. [ONSITE] ASSESSMENT REQUIREMENTS

§ 252.601. **[Onsite assessment] Assessment** requirements.

* * * * *

(d) The Department will provide the environmental laboratory with an **[onsite]** assessment report documenting any deficiencies found by the Department. **The Department may deny, suspend or revoke an environmental laboratory's accreditation in accordance with Subchapter G (relating to miscellaneous provisions) before issuing the assessment report or during the corrective action process.**

(e) An environmental laboratory shall submit a corrective action report to the Department within 60 calendar days from receipt of an **[onsite]** assessment report from the Department **[where] when** the Department has found deficiencies. The corrective action report **[shall document the corrective action taken by the laboratory to correct each deficiency.] must:**

(1) Document the corrective action taken by the laboratory to correct each deficiency and the time frame for completion.

(2) Include documentation demonstrating correction of the deficiencies as requested by the Department.

(f) An environmental laboratory seeking NELAP accreditation shall submit a corrective action report to the Department within 30 calendar days from receipt of the **[onsite]** assessment report from the Department **[where] when** the Department has found deficiencies. If TNI establishes a different time for submitting corrective action reports, the laboratory shall follow the time established by TNI. The corrective action report **[shall] must** document the corrective action taken by the laboratory to correct each deficiency.

(g) If any portion of the corrective action report is not acceptable, an environmental laboratory shall submit a revised written corrective action report within 30 calendar days from receipt of the Department's response. If the second corrective action report is not acceptable, the Department may revoke accreditation.

(h) Unless otherwise **required or** approved by the Department, **DEFICIENCIES SHALL BE CORRECTED WITHIN 120 CALENDAR DAYS OF RECEIPT OF THE ASSESSMENT REPORT.[deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.]** ~~**the environmental laboratory shall:**~~

~~**(1) Correct all deficiencies within 120 calendar days of receipt of the assessment report.**~~

~~(2) Implement and maintain the corrective actions within the time frames specified in the corrective action report or as mandated by the Department.~~

(i) The Department may extend the period of implementing corrective actions, for specific deficiencies, for a maximum of 30 calendar days upon receipt of the laboratory's written petition and corrective action report, when the laboratory must take one or more of the following actions:

(1) Purchase new equipment.

(2) Revise the quality manual.

(3) Replace significant laboratory personnel.

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.701. Denial of application.

(a) The Department will deny an application for accreditation, transfer of accreditation or application for renewal of accreditation under one or more of the following circumstances:

(1) The environmental laboratory is in continuing violation of or demonstrates an inability or lack of intention to comply with this chapter or other laws administered by the Department.

(2) The Department revoked the environmental laboratory's certificate of accreditation for all fields of accreditation for failure to correct deficiencies identified in an **[onsite]** assessment report within the previous 6 months.

(b) The Department may deny an application for accreditation, transfer of accreditation or application for renewal of accreditation for one or more of the following reasons:

* * * * *

(10) Failure to respond to an **[onsite]** assessment report with a corrective action report within the required **[timeframes] time frames**.

(11) Failure to submit an acceptable corrective action report in response to an **[onsite]** assessment **report** within the required time frames.

* * * * *

(16) Failure to meet the requirements of this chapter.

(17) Failure to maintain test instruments, equipment, supplies and reference materials that meet the specifications required to produce valid analytical results.

§ 252.702. Revocation.

(a) The Department will revoke an environmental laboratory's accreditation for a field of accreditation when, after being suspended due to failure to participate in a required proficiency test study or due to failure to obtain an acceptable result for a proficiency test study, the laboratory's analysis of the next proficiency test study results in a failed proficiency test study for that field of accreditation.

(b) The Department may revoke an environmental laboratory's accreditation, in part or in total, for one or more of the following reasons:

(1) Failure to respond to an **[onsite]** assessment report with a corrective action report within the required time frames.

(2) Failure to correct deficiencies identified during an **[onsite]** assessment of the environmental laboratory.

(3) Failure to implement corrective action **[related to] to correct** violations or deficiencies found during an **[onsite]** assessment.

(4) Failure of an environmental laboratory that has been suspended to correct all outstanding violations or deficiencies within 6 months of the effective date of the suspension.

(5) Failure to submit an acceptable corrective action report in response to an **[onsite]** assessment report within the required **[timeframes] time frames**.

* * * * *

(11) Analysis of proficiency test studies by personnel**, procedures, equipment, facilities, number of replicates and methods** other than **[the analysts] those** associated with the routine analysis of environmental samples in the laboratory.

* * * * *

(17) Failure to meet the requirements of this chapter.

(18) Failure to maintain test instruments, equipment, supplies and reference materials that meet the specifications required to produce valid analytical results.

(c) The environmental laboratory may continue to test or analyze environmental samples for those fields of accreditation not revoked.

(d) Within 72 hours of receiving notice of the revocation of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the revocation in writing of the revocation **[on a form]** ~~**in a manner approved by the Department**~~. **THE DEPARTMENT MAY REQUIRE THE LABORATORY TO USE SPECIFIC LANGUAGE IN THE WRITTEN NOTICE OR REQUIRE DEPARTMENT APPROVAL OF THE NOTICE BEFORE ISSUANCE.**

§ 252.703. Suspension.

* * * * *

(c) The Department may suspend a laboratory's accreditation in total or in part for one or more of the following reasons:

(1) Failure to comply with the reporting and notification requirements **[as specified in § 252.708 (relating to reporting and notification requirements)]**.

(2) Failure to implement a quality assurance program.

(3) Failure to employ staff that meets the personnel qualifications for education, training and experience **[as specified in § 252.302 (relating to qualifications of the laboratory supervisor)]**.

(4) Failure to submit an acceptable corrective action report in response to an assessment report within the required time frames.

(5) Failure to correct deficiencies identified during an assessment of the environmental laboratory.

(6) Failure to implement corrective action related to violations or deficiencies found during an assessment.

(7) Failure to maintain test instruments, equipment, supplies and reference materials that meet the specifications required to produce ~~results that meet the specifications required to produce~~ valid analytical results.

(8) Failure to analyze and report proficiency testing study results in accordance with § 252.501 (relating to proficiency test study requirements).

(d) A laboratory may continue to test or analyze environmental samples for those fields of accreditation not affected by the suspension.

(e) Within 72 hours of receiving notice of the suspension of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the suspension in writing of the suspension **[on a form]** ~~**in a manner approved by the Department**~~. **THE DEPARTMENT MAY REQUIRE THE LABORATORY TO USE SPECIFIC LANGUAGE IN THE WRITTEN NOTICE OR REQUIRE DEPARTMENT APPROVAL OF THE NOTICE BEFORE ISSUANCE.**

§ 252.704. Voluntary relinquishment.

(a) An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation or accreditation for fields of accreditation shall notify the Department in writing.

(b) An environmental laboratory that voluntarily relinquishes its certificate of accreditation shall ensure records are maintained in accordance with § 252.706 (relating to recordkeeping).

(c) Within 72 hours of voluntarily relinquishing its certificate of accreditation, the laboratory shall notify each of its customers affected by the voluntary relinquishment in writing of the relinquishment **[on a form]** ~~**in a manner approved by the Department**~~. **THE DEPARTMENT MAY REQUIRE THE LABORATORY TO USE SPECIFIC LANGUAGE IN THE WRITTEN NOTICE OR REQUIRE DEPARTMENT APPROVAL OF THE NOTICE BEFORE ISSUANCE.**

§ 252.705. Use of accreditation.

* * * * *

(c) Upon **expiration,** suspension, revocation or voluntary relinquishment of accreditation, a laboratory shall:

(1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to the laboratory's past accreditation status.

(2) Discontinue use or display of the Department's logo.

(3) Return **unexpired** certificates of accreditation to the Department within 48 hours.

(d) NELAP accredited laboratories shall accompany the Department's name or the **[NELAC/]**NELAP logo with the phrase "NELAP accredited" and the laboratory's accreditation number when using the Department's name or the **[NELAC/]**NELAP logo on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

(e) NELAP accredited laboratories may not use their NELAP certificate, NELAP accreditation status or **[NELAC/]**NELAP logo to imply endorsement by the Department or **[NELAC/]**NELAP.

§ 252.706. Recordkeeping.

(a) An environmental laboratory shall maintain records in an organized manner accessible by the Department.

(b) An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, proficiency test studies, initial demonstration of capability**[,]** or demonstration of continued proficiency. **These records include~~, but are not limited to,~~ the following:**

(1) Start and end dates and times of incubations, drying cycles, digestion, distillations, and the like, when a minimum or maximum time is specified by method, regulation or permit.

(2) Unequivocal link between the laboratory's sample identification number to the results of all associated quality control.

(3) Instrument identification.

(4) Identification of, or reference to, the standards, reagents, media, supplies, and the like, used during sample preparation or analysis, or both.

(5) The results of chemical [~~and~~] OR thermal preservation verifications or adjustments, or both.

(6) Date of sample preparation or analysis, or both.

(7) Time of sample preparation or analysis, or both, if the holding time for either activity is less than or equal to 72 hours.

(8) Manual calculations.

(9) Test results.

(c) All **[generated data, except data] records, except records** generated by automated **[data]** collection systems, shall be recorded promptly and legibly in permanent ink or in an electronic format. **[Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.]**

(1) The individual generating the record must be identified by initials or ~~signature~~ NAME and the individual making the observation must be identified by initials or ~~signature~~ NAME if different from the individual generating the record.

(2) Changes to records shall be made so that the original entry remains visible. The individual making the change shall BE IDENTIFIED BY NAME OR INITIALS ~~sign or initial and~~, date the correction AND INCLUDE THE REASON FOR THE CHANGE UNLESS CORRECTING A TYPOGRAPHICAL ERROR. These criteria also apply to electronically maintained records.

(d) Records required under this chapter shall be maintained for a minimum of 5 years unless otherwise specified.

(e) An environmental laboratory shall have a written plan that specifies how records will be maintained or transferred if the laboratory transfers ownership or terminates operations.

§ 252.708. Reporting and notification requirements.

(a) An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall:

(1) Meet the reporting and notification requirements of that chapter.

(2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for **[microbiological,]** inorganic nonmetals and trace metals analyses. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business.

(3) For organic **and radiochemical** analyses, review all sample analysis data within 7 days of acquisition of the initial sample results for organic analysis.

(4) For microbiological results, read all sample results within 30 minutes of the end of the incubation period.

(5) Analyze the laboratory control sample at a concentration at or below the maximum contaminant level.

(6) Report to the Drinking Water Environmental Lab Reporting system only those analytical test results that meet the method, regulatory and permit requirements for sample collection, preservation, holding time, sample analysis and quality control performance, unless the Department has specifically approved that the result may be reported.

(b) An environmental laboratory shall notify the Department, in writing, within 20 calendar days of a permanent change in laboratory supervisor.

* * * * *

pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

Bureau of Laboratories
Laboratory Accreditation Program

ENVIRONMENTAL LABORATORY ACCREDITATION REGULATION

25 Pa. Code Chapter 252
46 Pa.B. 5088 (August 20, 2016)
Environmental Quality Board Regulation #7-495
(Independent Regulatory Review Commission #3157)

Comment and Response Document

List of Commentators

ID	Name/Address
1	Richard Taylor Valley Forge Sewer Authority 333 Pawling Road Phoenixville, PA 19460
2	Barbara Loner Williamsport Sanitary Authority Laboratories 253 West Fourth Street Williamsport, PA 17701
3	David Brubacker Pure-Test Laboratory 736 E Lincoln Ave Myerstown, PA 17067
4	Glenn DiBernardi 200 Ross Street Plymouth Meeting, PA 19462
5	Larissa Hoover Cranberry Township WWTP 2525 Rochester Rd, Suite 400 Cranberry Township, PA 16066
6	Anngela Chapman 1803 Philadelphia Street Indiana, PA 15701
7	Genie Bausinger Milton Regional Sewer Authority 5585 State Route 405 PO Box 433 Milton, PA 17847
8	Debbie Shockley Allegheny Valley Joint Sewage Authority 24500 State Route 405 Pittsburgh, PA 15238
9	Robert J. Eppinger Philadelphia Water Department 1500 E. Hunting Park Avenue Philadelphia, PA 19124
10	Independent Regulatory Review Commission (IRRC) 333 Market Street, 14th Floor Harrisburg, PA 17101

General Support of Proposed Rulemaking

1. **Comment**: The proposed rulemaking is an improvement to the current regulation in allowing an absence of a laboratory supervisor for 21 consecutive days. (3)

   Response: The Department thanks the commentator for the support of this rulemaking.

2. **Comment**: The Department's addition of the items to be included in a test report, such as unique identifier code and identification of amendments and opinions were an improvement to the current regulation. (9)

   Response: The Department thanks the commentator for the support of this rulemaking.

Application and Supporting Documents

3. **Comment**: The current regulations state that an environmental laboratory seeking accreditation must apply to the Department in "writing on forms provided" by the Department. The regulation is being proposed to replace the phrase with "the format specified" by the Department. The commentator suggested that the Department specify what information must be included in the submissions and stated that § 252.205(a)(2)(iii)(A) also references forms. (10)

   Response: The Department did not intend to remove the requirement for submission of Department-provided application forms that outline the specific items and information to be submitted. §§ 252.201 and 252.203 of the final rulemaking have been amended to return the original language "on forms provided by the Department." The Department makes all forms available to the environmental laboratories, and the forms required to be submitted for compliance with final-form rulemaking are the same as those currently required. The "format specified" language remains in the final-form rulemaking in order to allow for multi-media submission of forms in the future.

Notification Requirements

4. **Comment**: The proposed rulemaking requires a laboratory to notify all customers within 48-hours of an expiration of their accreditation certificate "in a manner approved by the Department." It is recommended that the final rulemaking explain where the laboratory can obtain the information on what is an appropriate manner for providing notice to the customers. (10)

   Response: The Department amended the proposed language to remove "in a manner approved by the Department," and added "The Department may choose to require the laboratory to use specific language in the written notice or to require Department approval of the notice before issuance." Each case of loss of accreditation, including expiration of certificate, lapse in accreditation, suspension, and revocation, are unique to the particular laboratory and cannot be generalized. The revised language will allow the Department to

review the laboratory's proposed written notification or specify that certain language be used depending on the circumstances related to the loss of accreditation.

Microbiology Incubators

5. **Comment**: The revisions to section 252.306(j) regarding temperature distribution studies for incubators used for microbiology testing should be deleted or modified, suggesting that only incubator units that exhibit problems during an assessment should be required to undergo this study. Three commentators suggested that circulating water baths should be exempt from the distribution study. (1, 4, 5, 7, 10)

   Response: The Department has amended the final rulemaking to clarify that circulating water baths do not require the temperature distribution study. All other types of incubators used for microbiology testing can exhibit uneven temperature distribution and those that cannot demonstrate consistent temperature distribution do not meet the regulatory requirements for compliance. It is necessary for the laboratories to proactively evaluate the incubator's temperature distribution to ensure that all samples are properly incubated and the mandated temperatures. To allow laboratories to use malfunctioning incubation units until a Departmental on-site assessment discovers them is not an acceptable alternative.

6. **Comment**: Many laboratories do not staff their labs during holidays and weekends and the requirement to monitor incubators and water baths twice per day, at least four hours apart on these days is too stringent. A single temperature should be sufficient. (8)

   Response: The clarification language provided in the proposed rulemaking of the requirement to monitor and record the temperature of a microbiology incubator twice per day on each day that the incubator is in use is not different than the existing requirement for monitoring microbiology incubators. The laboratory is not required to staff the laboratory to manually make two measurements separated by four hours. The laboratory may employ a continuous monitoring device or a maximum/minimum reading thermometer to monitor the temperatures of microbiology incubators on days when the laboratory does not have staff physically on site.

7. **Comment**: A commentator requested clarification to the Department's use of the term "laboratory" in § 252.306(f)(8)(iv) when referring to a "working day" for all laboratory activities. (9)

   Response: The existing regulations require that the laboratory define its operations, trained laboratory staff, and their responsibilities in its quality manual, or other documentation. The laboratory must document this information as necessary to account for when trained and responsible laboratory staff are working in a laboratory and when a temperature is required to be taken for a non-microbiology incubator, water-bath, heating block or oven.

Request for Guidance Documents

8. **Comment**: Several commentators requested that the Department develop compliance assistance documents related to various requirements of the proposed rulemaking, specifically temperature distribution studies and sample receiving protocols. (2, 6, 7, 9, 10)

   Response: The Department is planning to develop technical guidance in collaboration with the Laboratory Accreditation Advisory Committee (LAAC) for procedures related to sample receiving and temperature distribution studies for microbiology incubators. Additional details were added to the order under "compliance assistance" to explain the Department's plans for preparation of technical guidance documents.

9. **Comment**: Does the Department plan to develop examples of data qualifier opinions and interpretation language that would be acceptable for inclusion in a test report? (9)

   Response: The Department will present this to the LAAC for discussion.

Laboratory Supervisor Qualifications and Requirements

10. **Comment**: The laboratory supervisor qualifications for basic microbiology testing should remain the same, and not specifically require four college semester credit hours in microbiology. (2, 3)

    Response: The proposed rulemaking did not add additional credit hour requirements for microbiology laboratory supervisors, but it does clarify that four of the 16 credit hours in biology must be in microbiology. Several public comments during the LAAC meetings and comments from the LAAC itself requested that the Department require that, in addition to four credits in microbiology, all laboratory supervisors must have taken a microbiology laboratory course. The Department believes that an individual who supervises a microbiology laboratory needs the microbiology education obtained during a college-level microbiology course and believes that four credits in microbiology, not specifically requiring a laboratory course work, is an acceptable compromise.

11. **Comment**: Technical knowledge obtained in a microbiology course is not necessary for a laboratory performing basic microbiology, such as Colilert testing, and requiring four microbiology course credits is unnecessary. (3, 6)

    Response: The techniques and methods included in the basic microbiology category are not limited to Colilert testing, and include technologies such as membrane filtration, multiple tube fermentation, and pour plate. These techniques require understanding and proficiency with sterile techniques, positive and negative controls, and specific media preparation and uses.

12. **Comment**: Requiring four credit hours in microbiology for a laboratory supervisor for basic microbiology will result in the laboratory community failing to be able to meet these new laboratory supervisor requirements. (3)

Response: Colleges and universities have many courses available on-line and four microbiology credits can be obtained in a single course. The Department has not required a lab be included in the four credits. The Department does not believe that the requirement for four credits in microbiology will diminish laboratory capability.

13. **Comment**: The Department should allow laboratory supervisors to be off-site and use remote electronic access to laboratory data/operations. Additionally, the Department should define 'absence' as 'off-site and not involved in or reviewing lab operations.' (3)

    Response: The Department extended the allowable time that a laboratory supervisor may be absent from 16 to 21 calendar days. Review of data is not the only responsibility of a laboratory supervisor. The laboratory supervisor is required to perform day-to-day supervision of the laboratory staff, operations, training, data generation, data reporting, etc. The Department will explore alternative ways to supervise laboratory staff and discuss these options with the LAAC to determine if a technical guidance document is necessary.

14. **Comment**: The laboratory supervisor provisions should allow for the substitution of years of experience for college credit hours. (6)

    Response: The LAAC and Department explored the option of allowing experience to substitute for college credit hours during the development of the proposed rulemaking in 2008 and again in 2015. Since experience is subjective, the Department, with assistance from the LAAC, was unable to determine how to evaluate experience for equivalency with college semester credits. However, many colleges and universities will evaluate experience and assign a credit value. The Department will accept credit hours assigned by an accredited college or university that are based on the individual's experience.

15. **Comment**: A commentator suggested that the laboratory supervisor provisions are not stringent enough, suggesting that:
    - a master's degree should not be substituted for one year of analytical experience,
    - the experience requirements for all laboratory supervisors should be increased from two years to four years citing that the accreditation requirements are getting more stringent and additional laboratory experience requirements would be a service to a laboratory supervisor,
    - the educational requirements for all laboratory supervisors should be increased to at least 24 semester credit hours of applicable education, and
    - a degree in engineering should be removed as an acceptable form of educational credentials. (9)

    Response: The Department's regulations are similar to those established by the National Environmental Laboratory Accreditation Program and believes the requirements of the rulemaking are adequate to ensure proper experience and education of a laboratory supervisor.

16. **Comment**: The new requirement, "if a method, regulation or program requires more stringent qualifications for education or experience, or both, the laboratory shall meet the more stringent requirements" should be added to § 252.304. (9, 10)

    Response: The Department has amended the final-form rulemaking to include this requirement in the personnel section, § 252.304.

17. **Comment**: The Department should reconsider the proposed change to the minimum number of years of experience for laboratory supervisors of inorganic non-metals, basic microbiology, and basic non-potable water. One commentator requested that the Department explain its rationale for why reducing the years of experience is adequate for the protection of the public and the Commonwealth's natural resources. (9, 10)

    Response: The methodologies and analytical technologies contained within these areas of supervision are less complicated and more easily mastered. The Department believes that one year of experience in these areas is sufficient to obtain mastery in these technical disciplines and will also enable smaller laboratories to more easily comply with the accreditation regulations, thus reducing the burden on small businesses and publicly owned laboratories.

18. **Comment**: The specific requirements required by the U.S. Environmental Protection Agency (EPA) for the certification of cryptosporidium be listed directly in the Chapter 252 regulation. (10)

    Response: The Department did not include these requirements directly in the Chapter 252 regulation to ensure that, if the EPA changes its requirements, the Department's requirements will not be obsolete or require amendment. The inclusion by reference will ensure that the Department's regulations are up-to-date. The Department will include these requirements in its application instructions to ensure that the applicant laboratories are aware of these requirements before submitting any applications for accreditation.

Volumetric Dispensing Devices

19. **Comment**: One commentator suggested that the removal of the term "mechanical" from § 252.306(f)(9)(i) will put a significant burden on the laboratory to verify non-Class A volumetric dispensing devices. (7)

    Response: The existing Chapter 252 requires that all mechanical volumetric dispensing devices be verified quarterly and any non-Class A volumetric dispensing devices be verified initially before use. The final-form rulemaking increases the requirement to verify all non-Class A glassware annually. This requirement was added to ensure that glassware that was not certified as Class A, which would include measuring devices that are self-marked in the laboratory, continue to meet the requirements of the standards and regulatory methods for volume. This annual verification requirement for non-Class A volumetric dispensing devices is consistent with the existing regulation for annual verification of non-Class A graduated sample containers included in § 252.306(f)(10).

Sample Handling and Receipt Protocols

20. Comment: Laboratories should be allowed to use currently published materials for sample handling, collection, and preservation in lieu of developing their own. (6, 10)

Response: The Department made changes to the final-form rulemaking to clarify that the laboratory must maintain documentation of sample collection and preservation requirements. The laboratory may choose to develop their own or use currently published materials from another source.

21. Comment: A single temperature is taken for sample refrigerators and not every sample bottle contained in the refrigerator, so a representative sample bottle should be allowed to be checked for temperature in a cooler. (8)

Response: The final-form rulemaking does not state that every sample bottle must be checked for thermal preservation. The Department is planning to develop technical guidance relating to sample collection, preservation, receipt, and storage.

22. Comment: Chemistry tests that do not require chemical preservation should not need to be measured for pH at the time of receipt. Also, when methods do not require the pH check of a sample, the pH should not be required to be checked, such as TSS. The cost of testing will likely be increased due to the increased cost associated with verifying the pH of all sample bottles. (8, 9, 10)

Response: Neither the existing regulations nor final-form rulemaking require that the pH of samples be taken at the time of receipt. The laboratory may develop its own procedures for checking and documenting the pH of samples, which may be at the time of receipt or throughout the life of the sample, as appropriate for the test. The Department included this provision at the recommendation of the Safe Drinking Water (SDW) Program and the EPA's instruction that an improperly collected sample is invalid and cannot be used for compliance purposes. Through discussions with the regulated community, the Department decided to limit the pH testing requirement to those samples that require a specific pH by method, regulation, or permit, and all SDW compliance samples. This compromise will ensure the protection of the public health but reduce the financial burden for non-drinking water samples. The regulated community participating in the public meeting were amenable to the compromise.

23. Comment: A commentator asked for clarification if the Department's "Request to Report Qualified Drinking Water Sample Results – Chemistry" system was the motivation for the proposed rulemaking change to require the pH of all samples be checked. (9)

Response: The Department's proposed rulemaking requirements relating to pH samples were not a result of the qualified drinking water request system.

24. **Comment**: The requirement in § 252.401(f)(1)(iii) is vague, stating that the laboratory should use the requirements or guidance in the method to determine if a sample needs to be checked for residual chlorine. (9, 10)

Response: The requirement to check samples for the presence of residual chlorine when its presence will compromise the validity of the test is a vital requirement to ensure that the sample results reported to the Department are valid for compliance purposes. The environmental laboratories are responsible for validating the sample upon receipt. A sample that contains chlorine, where chlorine will negatively impact the test, results in an invalid sample for compliance purposes. For example, the presence of chlorine in nitrate, nitrite, and bacteria/microbiological samples will negatively impact the validity of the final result. If a laboratory does not check for the presence of chlorine, it would not know if the sample result was negatively impacted and might report an invalid result for compliance purposes.

The Department worked diligently with the LAAC in crafting the language included in § 252.401(f)(1)(iii). The Department originally suggested that this provision require all samples to be tested for the presence of residual chlorine. However, the LAAC and other members of the public that attended the meetings were opposed to that language. Many tests are not impacted by residual chlorine, so the added cost of testing for residual chlorine would not justified. The LAAC suggested the language included in this provision as an alternative and the Department agreed that it would achieve the goal of ensuring valid final results. The Department did not attempt to list every test that is impacted by the presence of residual chlorine, nor did the LAAC request it, because to do so could unnecessarily limit the Department's enforceability of this requirement. Additionally, a list could quickly become obsolete if new test methods are added to other regulations, permits, or orders that also fall under the scope of the accreditation regulation.

25. **Comment**: A commentator requested guidance related to the requirements of § 252.307(j)(2), specifically asking if the laboratory is expected to provide written sampling instructions to non-laboratory personnel, or if the laboratory is expected to provide formal, documented training to non-laboratory personnel. (9)

Response: The final-form rulemaking states that the laboratory is to make sample collection and preservation instructions available to customers and clients that collect samples. The rule does not require the laboratory to provide any training to non-laboratory personnel.

26. **Comment**: All methods require or specify a temperature for sample collection or storage. Some methods do not require thermal preservation of samples, such as metals. The commentator asked if these samples will require a temperature measurement. (9)

Response: Yes, the final-form rulemaking does require a temperature measurement for all samples, but the regulation does not specifically require a temperature measurement of each sample container. The condition of the sample must be checked and documented upon receipt, and temperature of the sample is one of the observations that must be documented. The absence of a thermal preservation requirement for a particular sample or test does not negate the possibility that the samples might not be properly stored. By taking the

temperature of the sample, the observation of the condition of the sample would aid in indicating possible improper handling, inaccurate sample collection information, or other anomalies. The laboratory is responsible for ensuring that all necessary information is available for the data user to determine the validity of the sample results. The condition of the sample is the first step in validation of the final sample result. The Department will develop technical guidance to assist laboratories in meeting the requirements of sample receiving, handling, and storage.

Quality Control Requirements

27. **Comment**: A commentator requested clarification to § 252.404(d)(7) asking if these new requirements apply to purchased, pre-sterile dilution water for fecal coliform. The commentator requested consideration for laboratories that only test fecal coliform and do not have a history of method blank contamination. (8)

    Response: The language in paragraph (7) adds a requirement that the testing be performed by a laboratory accredited for the test being performed.

28. **Comment**: The language in § 252.404(h)(4) should include language that all positive and negative controls be processed along with an under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure. (9)

    Response: The Department added this language in Section 252.404(h)(7) in the final-form rulemaking.

29. **Comment**: Quality control checks should be performed before analysis of samples, before first use, as contamination identified during use would invalidate an entire sample batch. (9)

    Response: The Department agrees with the commentator, but decided not to amend the language of the proposed rulemaking in order to allow laboratories to determine when they perform the quality control.

30. **Comment**: A commentator requested clarification to § 252.304(b)(3)(vi)(D)(I) asking if the mid-point of the calibration range is acceptable or if the concentration tested must be less than the mid-point. (9)

    Response: The final-form rulemaking states that the concentration must be in the lower half of the calibration range. The mid-point is not in the lower half of the calibration range.

31. **Comment**: The relative standard deviation in § 252.304(b)(3)(vi)(IV) does not provide information relating to the measurement's accuracy. (9)

    Response: The commentator is correct. The rulemaking includes a statement in § 252.304(b)(3)(vi)(III) which requires laboratories to evaluate the individual recoveries in addition to the mean recovery of the control samples used when performing the demonstration of capability.

Handling of Expired Reagent, Standard, Media, and Reference Materials

32. **Comment**: The proposed language to segregate expired chemicals from unexpired chemicals should not be accepted and expired chemicals should be removed from the laboratory and discarded. (9)

    Response: The proposed language for segregation of expired chemicals was a compromise made by the Department in collaboration with the LAAC to allow laboratories to maintain expired chemicals for non-compliance purposes but to ensure that they could not be mistaken as acceptable for use for compliance testing.

33. **Comment**: The Department's allowance for re-certification of expired chemicals, materials, and positive and negative controls should be removed from §§ 252.404(h) and 306(h). (9)

    Response: The Department agrees with the commentator's suggestion to remove the language allowing for re-certification of expired materials and this provision has been removed in the final rulemaking.

34. **Comment**: The Department should explain how the approval referenced in § 252.404(h)(4) and (5) can be obtained or where information regarding the approval process can be found. (10)

    Response: The Department removed the allowance for re-certification of expired materials at the suggestion of another commentator.

Recordkeeping

35. **Comment**: Are scanned records equivalent to original paper records? (9)

    Response: A scanned record is an acceptable equivalent to original paper records. The Department requires that the laboratory ensure that all records, electronic or hard-copy, be maintained in a manner that ensures all changes and amendments are tracked and that all revisions are stored in a manner that is retrievable and meets the requirements of the Act and Chapter 252.

36. **Comment**: Section 252.706(c)(1) and (2) as written require initials or signature. The Department should consider removing the "signature" requirement and replacing with "printed name" or other identification because signatures are often not legible. (9)

    Response: The Department agrees with the commentator and the final-form rulemaking was changed to remove the written "signature" requirement.

37. **Comment**: A commentator asked how to document changes in electronic records as required by § 252.706(c)(2). Electronic records can be changed and the original entry deleted without being traced. (9)

Response: The language as written in the proposed rulemaking is not different than the language of the existing regulation. The proposed rulemaking separated this requirement into a separate sub-section. The Department requires that all changes to any record, electronic or otherwise, be tracked. The laboratory is responsible for keeping records that track all changes to records.

Data Usability

38. Comment: The language in § 252.402(f)(8)(i) and (ii) should be maintained because this is the criteria for accepting results associated with unacceptable calibration verifications. If it is the Department's concern that labs may continually operate with unacceptable calibration, then the Department should add clarifying language. (9)

Response: The Department removed this language because Chapter 252 provides a list of requirements for the environmental laboratories generating compliance data for any of the 12 statutes listed in § 252.3. The acceptability and usability of the data is not the responsibility of the laboratory. This section of the regulation was often referenced by the laboratories as rationale for not identifying quality control failures, mistakenly believing that this section exempted the use of data qualifiers. The Department's removal of this language does not change the Department's authority or responsibility for evaluating the usability of data.

Assessment and Corrective Action Requirements

39. Comment: The proposed rulemaking explains time frames for correcting deficiencies. Proposed § 252.601(h)(1) requires laboratories to correct all deficiencies within 120 days of receipt of the assessment report, but proposed § 252.601(h)(2) requires the laboratory to implement and maintain the corrective actions within the time frames specified by the Department. Further, these sections are confusing and unclear when deficiencies must be corrected. In what other manner would DEP mandate corrective action? (10)

Response: The final-form rulemaking was revised to remove the conflicting language and states "Unless otherwise required or approved by the Department, deficiencies shall be corrected within 120 calendar days of the assessment report." This allows the Department to determine if the violation is more severe and requires correction in less than 120 calendar days or if the violation is less severe and the laboratory can be allowed an extension for correction as allowed in § 252.601(i). Corrective action is required through a corrective action report after an on-site assessment, data audit, application review, complaint investigation, or other material review conducted by the Program. The Department's findings are usually described in an assessment report, which would trigger the requirements of § 252.601 for corrective action. Corrective action is required whenever the laboratory fails to meet the requirements of the regulation. The consequences and rationale for Department action are outlined in subchapter G (relating to miscellaneous provisions).

General Comments

40. Comment: The Department did not propose to amend § 252.3 (relating to scope), but that several of the references contained within § 252.3 are out of date. (10)

Response: The Department reviewed the citations contained within § 252.3 and made the necessary corrections to update these references.

41. Comment: Two commentators included several suggestions for editorial changes to be consistent with the *Pennsylvania Code & Bulletin Style Manual* and other editorial suggestions. (9, 10)

Response: The Department reviewed the regulation and editorial comments and made changes where applicable and necessary.

42. Comment: The Regulatory Analysis Form (RAF) should be more detailed in response to question #12 regarding how the final rulemaking compares to other states regulations and how it will impact PA's ability to compete with other states. (10)

Response: Additional detail is provided in the RAF for item #12.

General Comments Not Related to the Proposed Rulemaking

43. Comment: The Department's laboratory accreditation personnel do not meet the requirements of a Chapter 252 laboratory supervisor and laboratory assessments are conducted by unqualified laboratory assessors. (3)

Response: The Department ensures that its laboratory accreditation officers are trained in accordance with the EPA's requirements for SDWA Certification Officers and the National Environmental Laboratory Accreditation Program's (NELAP) requirements for accreditation officers and all laboratory accreditation staff meet the minimum education and experience requirements of the State Civil Service Commission for Chemist 2 and Microbiologist 2 job classifications.

44. Comment: A proposed list of data qualifiers from PA-DEP should be discussed more formally during the LAAC meetings. Does the Department intend to standardize data qualifier language? (9)

Response: The Department has commenced working with the LAAC to standardize data qualifier language. That endeavor will continue after the technical guidance documents are developed for sample receiving and microbiology incubator studies.

45. Comment: The Department should use the 2012 MUR format for referencing methods using an approval year instead of the edition, stating that this would make all laboratory documentation consistent from internal documentation through to, and including, the sample data reporting to external customers. (9)

Response: The Department uses the edition number, when appropriate, to identify SDWA mandated methods where the edition number is necessary to determine which method technology is used in the laboratory. The Department does not specifically require an edition or approval year when identifying test results to customers or clients.

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

May 11, 2017

David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Final Rulemaking: Environmental Laboratory Accreditation (#7-495)

Dear Mr. Sumner:

Pursuant to Section 5.1(a) of the Regulatory Review Act, please find enclosed the Environmental Laboratory Accreditation final rulemaking for review and comment by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (EQB) adopted the final rulemaking at its April 18, 2017 meeting.

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed the Environmental Laboratory final rulemaking for review and comment by the House Environmental Resources and Energy Committee (Committee). The Environmental Quality Board (EQB) adopted the final rulemaking at its April 18, 2017 meeting.

The enclosed final-form rulemaking amends the Environmental Laboratory Accreditation Regulations in 25 Pa. Code Chapter 252 which set forth the requirements that laboratories must meet to be accredited to perform testing for 12 environmental statutes. This final-form rule amends the following areas of the laboratory accreditation regulations: fee structure; definitions; National Environmental Laboratory Accreditation Program (NELAP) equivalency; laboratory supervisor qualifications; quality assurance/quality control procedures; analytical procedures; record keeping procedures; and notification requirements.

The primary amendment included in the rule is the revision to the fee structure. The existing fee structure does not ensure that the costs of administering the accreditation program are covered by the fees collected from the accredited laboratories. The amended fee structure accounts for the number of laboratories currently seeking accreditation, the size of the laboratory's scope of accreditation, and the amount of time and cost associated with administering the accreditation program. In 2014, the Laboratory Accreditation Program (LAP) began providing accreditation services for cryptosporidium, which imposes additional costs not recovered by the fees promulgated in 2010. The amended fee structure separates the basic microbiology category from complex microbiology and assesses two different fees based on the complexity of the accreditation activities.

Other amendments include clarifications of existing requirements, such as performing temperature distribution studies for microbiology incubators; maintaining sample collection and handling procedures/instructions for sample collectors; verifying and documenting the condition of the sample upon receipt; explaining that the Department of Environmental Protection (DEP or Department) will not accept proficiency test study results that are not performed in accordance with Chapter 252 requirements; and clarifying DEP's authority to suspend, revoke, or deny accreditation based on non-compliance found during an on-site assessment.

The rulemaking removes or amends several overly restrictive or cost prohibitive requirements, such as reducing the amount of hands-on analytical experience that is necessary for a laboratory supervisor for basic microbiology, basic non-potable water, and inorganic non-metals; allowing college semester credit hours in health physics and chemistry instead of limiting credits in chemistry for radiochemistry laboratory supervisors. The rule allows DEP to develop procedures and practices to conduct laboratory assessments offsite and use other technological advances instead of requiring all assessments to occur onsite at the laboratory. The rule also allows DEP to suspend a laboratory's accreditation or violations relating to assessment requirements instead of requiring revocation of the laboratory's accreditation

The final-form rule also adds sections to the NELAP Equivalency portion of section 252.5 to ensure that all laboratories generating compliance data for DEP are doing so under the same requirements, specifically, the requirements for sample collection, acceptance, and handling.

Those affected by this regulation include any person, facility, or group that performs testing or analysis on drinking water, non-potable water, and/or solid and chemical material environmental samples required for compliance with 12 enumerated environmental statutes. Approximately 5,000 laboratories are regulated under Chapter 252, but the number of entities that will be required to change procedures due to these regulatory amendments is approximately 450. LAP designates small, medium, and large laboratories based on scope of analytical testing, thus there are approximately 300 small laboratories, 80 medium laboratories and 70 large laboratories.

The technical expertise, experience with regulatory programs, and size of the facilities affected by these regulations vary greatly. Most of the amendments include clarifications to the current requirements rather than wholly new requirements. The smallest facilities are expected to have the least amount of technical expertise and have been and will continue to be the primary focus of compliance assistance efforts.

Overall, the final-form rulemaking will allow for better understanding and increased compliance with requirements and thus result in improved overall quality of the data produced by environmental laboratories.

Comments were received from ten commentators, including the Independent Regulatory Review Commission. Most of the comments received during the public comment period related to requirements for microbiology incubation units, laboratory supervisor qualifications, sample acceptance and receipt, expired materials, and a general request for technical guidance documents from DEP to describe and detail compliance options with the new requirements. No comments were received relating to the amended fee schedule. All comments were carefully

considered and corresponding amendments were made to the final-form rulemaking, as appropriate.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the proposed and final-form regulations. The LAAC held public meetings on December 11, 2014, March 11, 2015, June 24, 2015, September 30, 2015, and December 2, 2015 to review DEP's proposed drafts of the Chapter 252 regulations. The LAAC met again on December 7, 2016 to discuss the public comments from the proposed rulemaking and DEP's draft final regulations. The LAAC and other members of the public provided advice and insight to DEP during these meetings. DEP considered all, and agreed with most, of the recommendations made by the LAAC. On December 7, 2016, the LAAC voted unanimously to concur with DEP's recommendation that the final Chapter 252 amendments move forward to the EQB for consideration.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed final-form rulemaking under Section 5.1(e) of the Regulatory Review Act.

Please contact me by e-mail at ledinger@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,

Laura E. Edinger

Laura Edinger
Regulatory Coordinator

Enclosures

0120-FM-PO0011 6/2015

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7- 495

SUBJECT: Environmental Laboratory Accreditation

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Regulation with Notice of Proposed Rulemaking Omitted
- ☐ 120-day Emergency Certification of the Attorney General
- ☐ 120-day Emergency Certification of the Governor
- ☐ Delivery of Tolled Regulation
  - a. ☐ With Revisions
  - b. ☐ Without Revisions

RECEIVED
MAY 11 2017
Independent Regulatory Review Commission

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/11/17	Shelly Weaver	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative John Maher
5/11/17	Will. Mag	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Mike Carroll
5/11/17	Patti Cahoy	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
5/11/17		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator John Yudichak
5/11/17	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION David Sumner
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-

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AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

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5/11/17		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
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